YM303i

3 Channel Resting ECG System

Operator's Manual

L09521 Revision 02

MEDIANA

Note

The information in this manal applies to YM303i 3channel resting ECG system. Due to continuing product innovation, specifications in this manual are subject to change without notice.

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Chapter1.

Important Product information

Chapter1. Important Product Information

Read all information below and operating instructions before using YM303i to avoid injury or harm. For detailed operating instructions read followed chapters.

1.1 General information

- The product **YM303i** bears the CE marking CE 0434 indicating its conformity with the provisions of the Council Directive 93/42/EEC (as amended by 2007/47/EC) concerning medical devices and fulfills the essential requirements of Annex I of this directive. It is class Ⅱa (MDD) equipment.
- The product is designed to comply with IEC60601 requirements. It is a protection class I, type CF device.
- The product complies with the electromagnetic immunity requirements of standard IEC 60601-1-2/EN 60601-1-2 "Electromagnetic Compatibility-Medical Electrical Equipment".
- The radio-interference emitted by this device is within the limits specified in CISPR11/EN55011, class B.
- This manual is an integral part on the device. It should always be kept near the device. Close observance of the information given in the manual is a prerequisite for proper device performance and correct operation and ensures patient and operator safety.
- This manual is in conformity with the device specifications and standards on safety of electro-medical equipment valid at the time of printing. All rights are reserved for device, circuits, techniques, and software program appearing in this manual.
- To ensure patient safety, the specified measuring accuracy, and interference-free operation, we recommend using only original MEDIANA components. The user is responsible for application of accessories from other manufacturers.
- The warranty does not cover damage resulting from the use of unsuitable accessories and consumables from other manufacturers.
- The safety information given in this manual is classified as follows:

Warning: Indicates a hazard.
If not avoided, the hazard can result death or serious injury.

Caution: Indicates a potential hazard
If not avoided, this hazard may result in minor personal injury and/or product/property damage.

1.2 Safety information

Warning: Indicates a hazard.

If not avoided, the hazard can result death or serious injury.

- Avoid humidity, high temperature, dust in the air, salt or sulfuric material and avoid the unventilated place or the direct sunlight.
- Avoid vibration or mechanical shock.
- Avoid fire and explosion hazard. An explosion hazard may result from the use of flammable anesthetics, skin cleansing agents and disinfectants.
- Dispose of the packaging material, observing the applicable waste control regulations. Keep the packaging material out of children's reach.
- Check the voltage rating before you connect the device to an electrical outlet to ensure that the required voltage and frequency are those o indicated on product label or manual.
- In order to secure electrical safety, connect the power cable to an independent grounded electrical outlet only.
- If use multi-tap inevitably, use the one provided with earth pin by all means.
- If in doubt the integrity of the AC power source, the device must be operated from its internal battery.
- If devices connected to other devices or to parts of systems only when it has been made certain that there is no danger to the patient, the operators, or the environment as a result.
- Connect equivalent ground when use with other devices.
- It is possible that noises beyond guaranteed from immunity requirements of IEC60601-1-2, any radio frequency transmitting equipment and other sources of electrical noise such as cellular phones, can result in disruption of the device operation.
- Remove all the metal accessories of patient wears before the perform measurement.
- Do not use the device or any accessories if damaged. .
- Operator shall not touch patient and device simultaneously.
- During use of device, avoid contact between the metal part of device and the patient.
- Do not touch the patient, the patient cable, or the device while defibrillator is operating.
- When connect the patient with several electrical device, it may increase electrical shock hazard by leakage current.
- Do not connect the electrode or the patient cable with any other electrical device or its ground terminal.
- Disconnect the device from the power line before cleaning or disinfecting its surface.
- Do not use this device along with high-frequency electrical operative equipment, since it may damage the equipment or the patient.

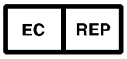
- When cleaning the device, pay special attention so that cleaning liquid or any liquid may not soak into the inside of device. If any liquid soak into the inside of device, do not connect power line, do not use device, and contact service center.
- A qualified physician must overread all interpretation results and computer-generated tracings. Computerized interpretation is only significant when used in conjunction with clinical findings.
- Due to the risk of electrical shock, do not open the cover of the equipment unless absolutely necessary and disassembly of the machine should be done only by a maintenance worker who has the license from MEDIANA Co., Ltd.
- If smoke or unusual odors are detected, disconnect the power line and contact MEDIANA service center. See your user's manual for the appropriate contact.
- For best product performance and safety, use only accessories supplied or recommended by manufacturer.

Caution: Indicates a potential hazard

If not avoided, this hazard may result in minor personal injury and/or product/property damage.

- The electrocardiograph is intended to be used in a hospital and hospital facilities environment by trained medical personnel
- It was designed as Class I Protection, Type CF device. Therefore, the electrocardiograph is suitable for direct application to the cardiac.
- Make arrangement so that patient cable may not be twisted.
- The electrodes passed the toxicity test performed by a certified institute. However, they may cause problems with the skin when applied for an excessive period of time. Therefore, use them for measurement only.
- Clean up where the electrode will be attached by the wet with water(No alcohol or Hydrogen Peroxide) cotton wool.
- When the defibrillator is operation, the ECG signal may be interfered by the defibrillator operation, but it will be recovery when the defibrillator stops working.
- It is recommended to use the device at the environment where AC rated power is provided, and it is required to use the charging battery power source during emergency situation or during inevitable movement. On the other hand, when using battery, charge it for at least 6 hours and then use it.
- After operation has finished, in order preventing malfunction, clean the equipment and accessories.
- When cleaning the equipment, wipe it with sponge or something like that wetted with soapy water and never use the detergent using alcohol, ammonia or acetone as main ingredient.
- Handle the electrode with care so that its inside surface is not scratched.

1.3 Symbols marked on YM303i

Symbol	Description / Function
	Classification of electrical protection symbol: This symbol means the device is CF type(cardiac floating) protection applied.
	EU-Consult instructions for Use: This symbol means read manuals or descriptions from manufacture.
	EU-Warning or Caution: This symbol indicates hazard.
	High Voltage Caution: This symbol means high voltage parts included.
	EU-Manufacturer information: The manufacturer's information shows with this symbol.
	EU-Made Date: The made date of the product shows with this symbol
	*EU- Representatives information:* The manufacturer's EU representative information shows with this symbol.
	EU-Model name: This symbol means model name of product.
	EU-Lot number: This symbol means lot number of product.
	EU-Serial Number: This symbol means serial number of product.
	EU-Electronics and Battery Disposal Information: This symbol means that the product and battery should be recycled separately from household waste. When this product reaches its end of life, follow the local laws and regulations of disposal. The improper disposal of waste electronic equipment from the consumer may be subject to fines.
	SD card symbol: This symbol indicates SD card slot.
	GND symbol: This symbol means equivalent ground terminal
	Network symbol: This symbol means TCP/IP terminal
	USB device symbol: This symbol means Universal Serial Bus terminal.

1.4 Symbols on the Packaging of YM303i

Symbol	Description / Function
	Humidity limit information: This symbol means acceptable range of humidity, during it is transported and stored. (10% to 95%, non-condensing)
	Temperature limit information: This symbol means acceptable range of temperature (-20℃ to 60℃)
	Keep dry: This symbol means that the product avoid expose in rain or wet environment during it is transported and stored.
	Upper side symbol: This symbol indicates up-side of package. When the packages moved or stored keep the direction. The point of arrow is up-side.
	Recycle symbol: This symbol means the package made from recycled materials

1.5 Service information

Technical support and purchase of accessories are available at below contacts.

MEDIANA Co., Ltd.
TEL (+82) 70-7092-9967
FAX (+82) 33-742-5483

Chapter2.

Getting start

Chapter2. Getting start

Warning:
To avoid injury or harm, read all operating instructions in this manual and safety information in *chapter1. Important Product Information.*

Caution:
The YM303i is intended to be used in a hospital and hospital facilities environment by trained medical personnel.

2.1 Intended use

The YM303i is to acquire multi-channel ECG signals from adult patients from body surface ECG electrodes and to record, display, analyze, and store these ECG signals for review by the user. The YM303i is to be used in healthcare facilities by trained healthcare professionals. Analysis of the ECG signals is accomplished with algorithms that provide measurements, data presentations, graphical presentations, and interpretations for review by the user.
The interpreted ECG with measurements and interpretive statements is offered to the clinician on an advisory basis only. It is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, the ECG tracings, and other clinical findings. A qualified physician is asked to overread and validate (or change) the computer-generated ECG interpretation.

2.2 YM303i Overview

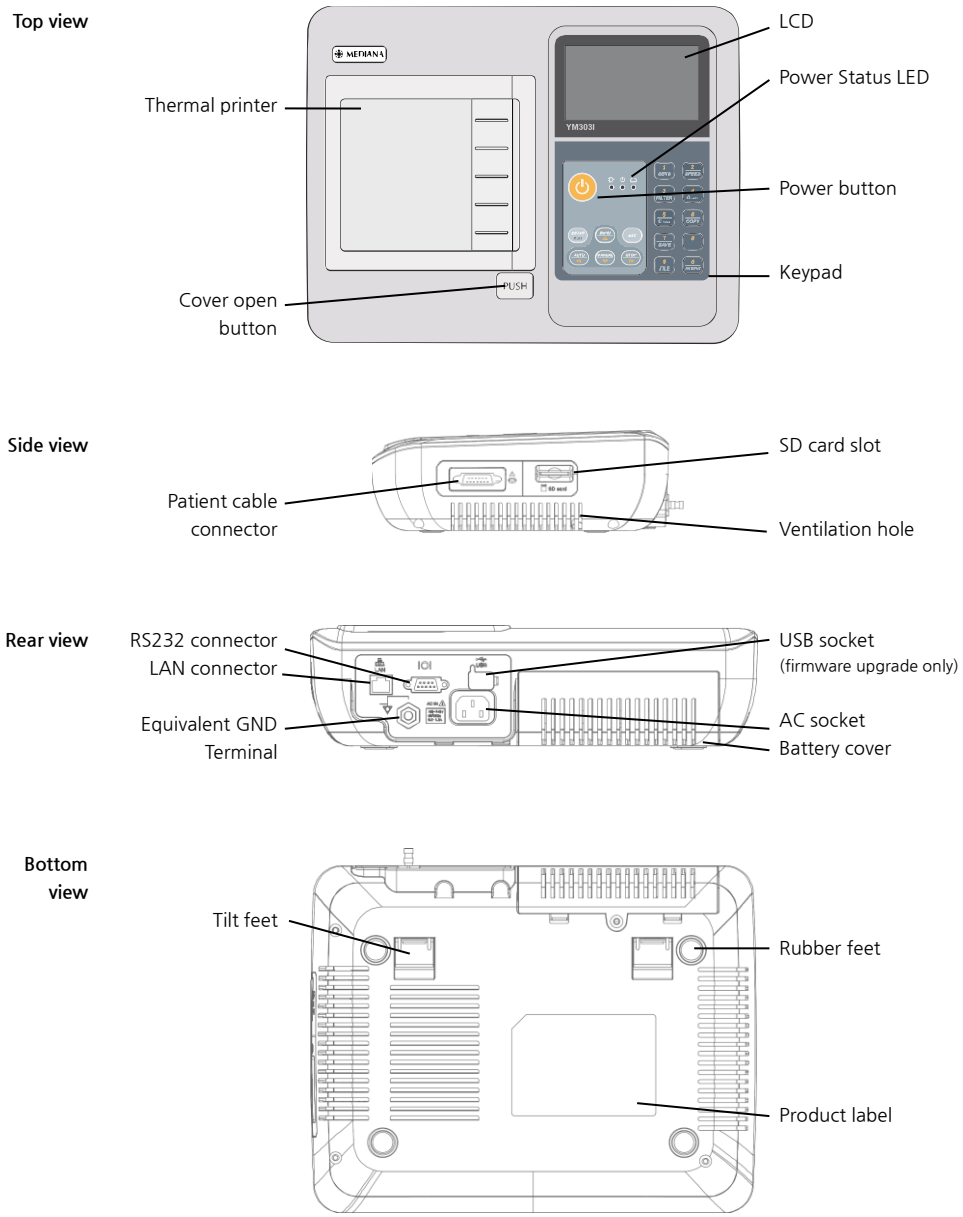


Figure2-1 YM303i Overview

2.2.1 Power switch

The YM303i has a soft power button. Press to switch on/off the device. When off the device press longer.

2.2.2 Power Status LED

The YM303i has 3 power status LEDs

Table 2-1. Power Status LEDs

LED	Name	Description / Function
	AC plugged-in	**Off** Disconnect AC power line **Solid Green** Connect AC power line
	Power-On	**off** The device is off **Solid Green** The device is on
	Battery Charging	**Off** Battery Operation(at device On) **Blinking Orange** The battery is charging **Solid Orange** The battery is fully charged

2.2.3 Keypad

The buttons of YM303i have more than one function. There is an example 'button 1' works as **number 1** at text input situation and **gain hotkey** at home screen.

Table 2-2. Keypad of YM303i

Button	Description / Function
	1 Number 1 **Gain*** Adjust input gain(5, 10, 20mm/mV)
	2 Number 2 **Speed*** Adjust printing speed(5, 10, 25, 50mm/sec)
	3 Number 3 **Filter*** Hotkey for enter to filter select menu
	4 Number 4
	5 Number 5 **G mode*** Hotkey for change grouping of ECG waveform displayed on LCD screen
	6 Number 6 **C mode*** Hotkey for change channel of grouped ECG waveform displayed on LCD screen
	7 Number 7 **Save*** Hotkey for last acquisition data save
	8 Number 8 **Copy*** Hotkey for extra report printing of last recorded ECG at automatic mode.
	9 Number 9 **File*** Hotkey for ECG data management.

Button	Description / Function
	0 Number 0 **Patient*** Hotkey for enter to patient data editor
	ENTER confirming of a selected parameter **RUN*** Hotkey for make a report
	ESC go to upper menu or exit menu **STOP*** Stop printing(at manual mode), Stop acquisition, or printing(at automatic mode)
	MENU* enter to configuration menu ▲ Up cursor: press to move the cursor up
	AUTO* Auto mode: press to select to automatic mode ◀ Left cursor: press to move the cursor left
	▼ Down cursor: press to move the cursor down
	Manual* Manual mode: press to select to manual mode ▶ Right cursor: press to move the cursor right

*It works at home screen.

2.3 YM303i contents

a. YM303i Device(1EA)

b. Clamp Electrodes(1Pack:4EA)

c. Chest Electrodes(1Pack:6EA)

d. Patient Cable(1EA)

e. Roll Paper(1Roll)

f. Z-fold Paper(1EA)

g. Program and Manual(1EA)

h. AC Power Cable(1EA)

Figure 2-2 YM303i contents(Basic)

* The above pictures vary from the original in some points.

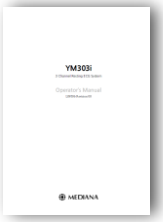
Options

i. SD Card

j. Serial Cable(1EA)

k. Ground Cable(1EA)

l. Manual(1EA)



m. Disposable Adapter(1Set:10EA)

n. Disposable Electrode(Round)

o. Disposable Electrode(Tab)

Figure 2-3 YM303i contents(Options)

* The above pictures vary from the original in some points.

2.4 YM303i Ordering Information

Table 2-3 YM303i Ordering Information

No.	Ordering Code	Name	Unit
b	A10001	Clamp Electrodes	1Pack(4EA)
c	A10102	Chest Electrodes	1Pack(6EA)
d	A00000	Patient Cable(IEC)	1EA
	A00003	Patient Cable(AHA)	1EA
e	A20100	AC Power Cable(Korea)	1EA
	A20200	AC Power Cable(EU)	1EA
f	A50001	Roll Paper	1Box(10Roll)
g	A50002	Z-fold Paper	1Box(10EA)
h	L09521	Operator's Manual(English)	1EA
	L09522	Service Manual(English)	1EA
i	A40001	Program CD	1EA
j	D00000	SD Card	1EA
k	A30000	Serial Cable	1EA
l	A20000	Ground Cable	1EA
m	A00004	Disposable Adapter(IEC)	1Pack(10EA)
	A00005	Disposable Adapter(AHA)	1Pack(10EA)
n	A10200	Disposable Electrode(Round)	1Pack
o	A10201	Disposable Electrode(Tab)	1Pack

2.5 Installation

1) Install the YM303i in place where avoid humidity, high temperature, dust in the air, salt or sulfuric material and avoid the unventilated place or the direct sunlight.
2) Connect provided AC power cable with the YM303i.

3) Plug the AC power cord to independent grounded AC outlet.(recommended)

Connect the ground cable when use no grounded AC outlet.

*Don't arrange in parallel the power line and the patient cable it may makes noise in signal.

4) Press the power button to turn on the YM303i.

The power button is pressed Power-On LED(⏻) turn on and shows up the startup screen and the boot-up screen.

5) When booting sequence complete the home screen shows up in LCD.

If the home screen shows up it means the YM303i it ready for acquisition, monitor input signals and enter to configuration menus.

*See the Screens description for detail information.

*The home screen is may be different because of setting value.

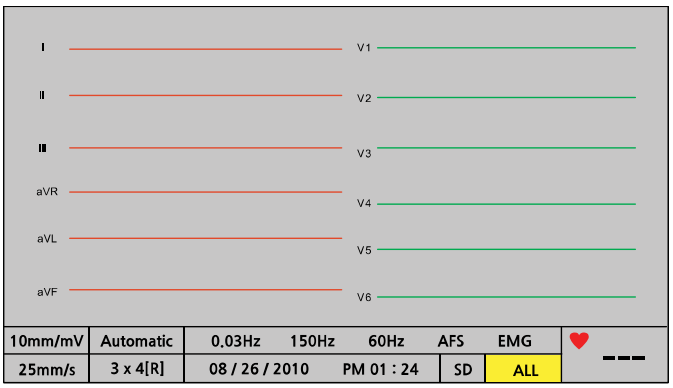


Figure 2-4 home screen

Warning: **Shock Hazard**

- To ensure patient safety, the conductive parts of the ECG electrodes (including associated connectors) and other patient-applied parts should not contact other conductive parts, including earth ground, at any time.
- For reasons of patient safety, use only the original patient cable provided by MEDIANA Co., Ltd.

2.6 Connecting with patient

1) Lay down the patient on the bed and get rest.

2) Connect to the patient with the YM303i

Use the patient cable provided by MEDIANA Co., Ltd. and plugin the patient cable connector on the right side of the YM303i.

3) Connect the electrodes with leads.

Figure 2-5 shows chest electrode and clamp electrode. Connect Chest electrodes with lead C1 to C6 and Clamp electrodes with lead R, L, F and F. Screw to clockwise the hold screw of electrode for tight contact. Loose contact may cause noise on the ECG signal.

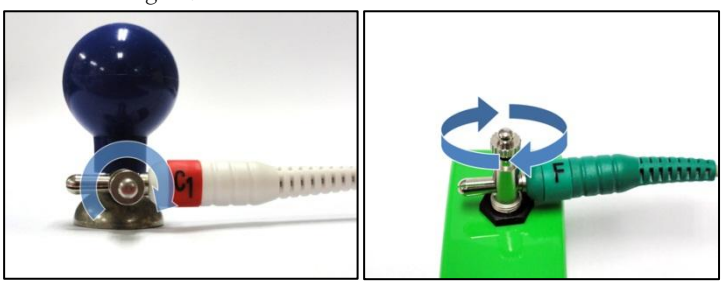


Figure2-5 chest electrode(left), clamp electrode(right)

4) Locate the patient bundle on the center of the patient.

5) Attach the electrode to the body of patient.
The figure 2-6 shows the position of electrodes it is important to acquit or analyze of ECG signal. The electrodes positions and contact conditions affect the ECG signal quality and interpretation result. If patient's skin is too dry put some water, and if too much hair at the electrode attaching place then it needs shaving. Bad contact condition with skin and electrode may cause added noise on the ECG signal.

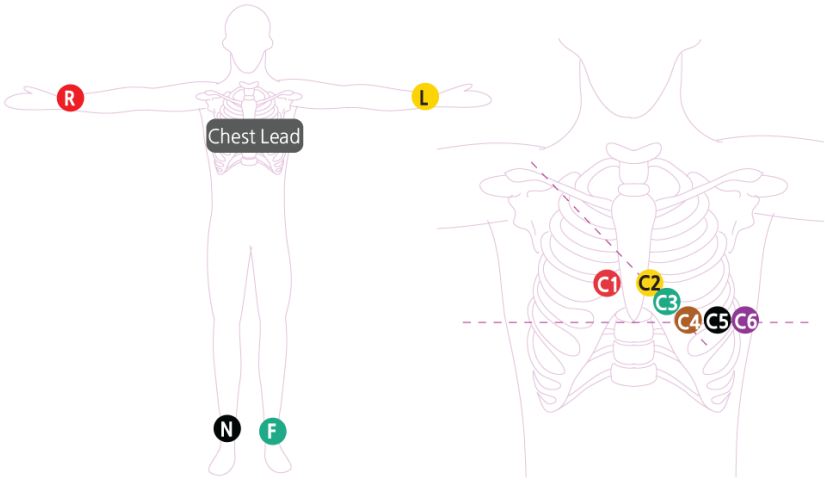


Figure 2-6 ECG Lead system

All leads has label as shown in figure 2-6. Match the electrodes and the leads as shown in figure 2-6 and label difference between IEC and AHA shown in Table 2-4. If the connection is wrong it may makes bad effect on signal or result.

Table 2-4. IEC lead and AHA Lead

	Limb Lead				Chest Lead					
IEC	R	L	N	F	C1	C2	C3	C4	C5	C6
AHA	RA	LA	RL	LL	V1	V2	V3	V4	V5	V6

Chapter3.

Operating

Chapter3. Operating

3.1 Screens

At this chapter it will be described major screens of the YM303i and its functions.

3.1.1 Startup screen

The figure 3-1 shows the startup screen of the YM303i. It is the first screen on the LCD after the device is turned on. Startup screen shows BIOS version and waiting progress bar for the firmware update event.
*For more detail information of the firmware update, refer to the firmware update section.

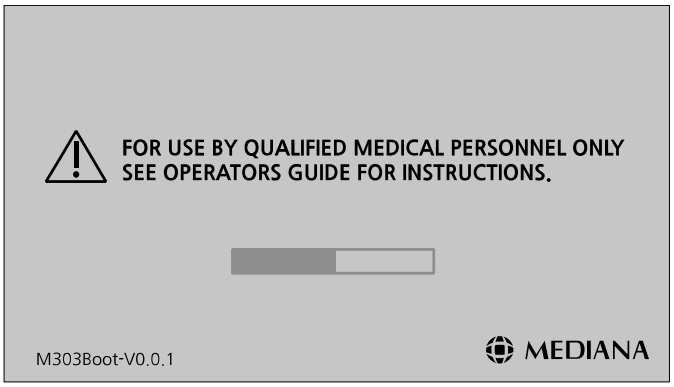


Figure 3-1. Startup screen

3.1.2 Boot Screen

The figure 3-2 shows the boot screen. The YM303i is ready to operate during this screen shown. Boot screen shows model name and firmware version of the device.

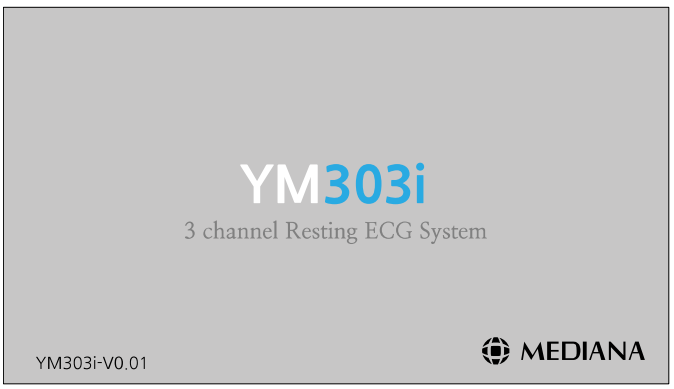


Figure 3-2. Boot screen

3.1.3 Home Screen

The figure 3-3 shows Home screen of the YM303i. The home screen shows parameters of the YM303i and ECG waveforms.

**It may look different, depending on the parameters setting and input signals.*

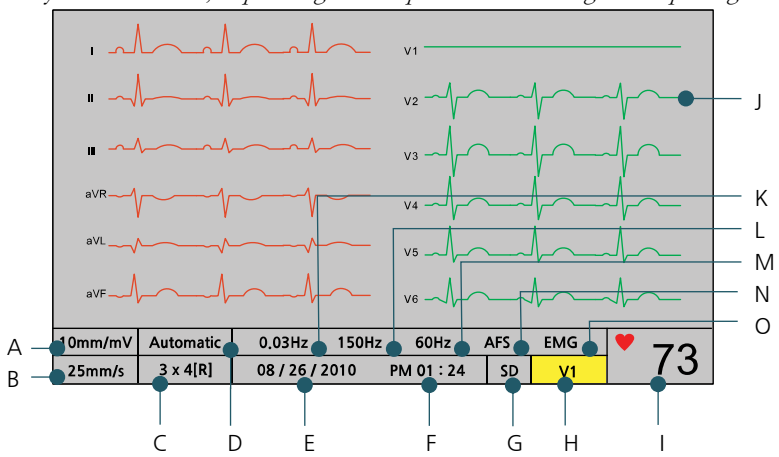


Figure 3-3 The Home screen

A	Gain	I	Heart Rate
B	Paper Speed	J	ECG Wave
C	Print format	K	Low Pass Filter
D	Operation Status	L	High Pass Filter
E	Date	M	AC Filter
F	Time	N	Anti-Floating System enabled
G	SD Card Insert	O	Muscle Filter Enabled
H	Lead Fail Detection		

3.2 ECG measurement

3.2.1 Automatic mode

> ***Warning: Interpretation Hazard***
> A qualified physician must overread all interpretation results and computer-generated tracings. Computerized interpretation is only significant when used in conjunction with clinical findings.
> Physiological condition of the patient may effect on interpretation results.

1) **Turn on the YM303i**

Press the **Power** button to turn on the YM303i.

2) **Switch to the automatic mode**

Press the **AUTO** button to Automatic mode.
**Operation mode setting available only home screen*

3) **Connect the YM303i with a patient**

Put electrodes to a patient and connect with patient cable. For more detail information refers to the 'Electrodes position and Leads connection'.

4) **Press the Run button to begin ECG signal recording.**

In automatic operation mode, recording process has 3 states. The state is shown on status cell.

a) **Acquisition:** Getting ECG signal from the patient.
b) **Analysis:** Analysis and interpretation the signal.
c) **Printing:** Printing the ECG waveform and result.

If you want stop the process, press the **STOP** button.

3.2.2 Manual mode

This operation mode provides continuous ECG record without interpretation.

1) **Turn on YM303i**

Press the **POWER** button to turn on the YM303i. If already turned on press the **ESC** button to show the home screen.

2) **Switch to the Manual mode**

Press the **MANUAL** button to Manual mode.
**Operation mode setting available only home screen.*

3) **Connect the YM303i with a patient**

Put electrode to a patient and connect with patient cable. For more detail information refers to the 'Electrodes position and Leads connection'.

4) **Press the RUN button to begin ECG signal recording.**

In manual operation mode, recording begins the **RUN** button pressed immediately.

5) **Press the STOP button to stop recording.**

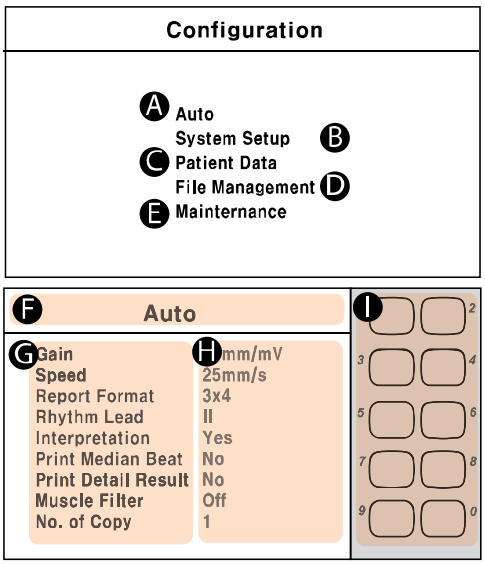
In manual operation mode, the recording will continue the **STOP** button is pressed.

Caution: Do not print more than 30min in the manual mode. It may result in break down or reduction of life time of the device.

3.3 The Setup Menu

Press the **MENU** button at Home Screen to enter the Configuration menu.

The Figure 3-4 shows Configuration menu and submenu of YM303i. Move the cursor on items using Up cursor key or Down cursor key, and press the **ENTER** button to open the submenu.



- **A** Enter to submenu of Auto mode. This item is toggled by current operation mode. If the current operation mode changes to Manual mode, this item will be toggled to Manual.
- **B** Enter to submenu of System Setup.
- **C** Enter to submenu of Patient Data edit.
- **D** Enter to submenu of File Management.
- **E** Enter to submenu of Maintenance.
- **F** The title of selected menu.
- **G** The parameters list of submenu.
- **H** Current setting value.
- **I** Selectable options of current parameter.

Figure 3-4 The Menu Screen of YM303i(Up: main configuration menu, Down submenu)

3.3.1 Automatic mode Menu

1) Switch to Automatic operation mode

This menu is dependent the operation mode. It is necessary switch to Automatic mode. If press the **AUTO** button it will be switched the operation mode to Automatic mode.

2) **Press the MENU button to enter the configuration menu.**

If press the **MENU** button at Home-Screen, it will be shown the Configuration menu. Move the cursor on **Auto** and press the **ENTER** button to enter the submenu of Auto configuration.

**If other function is running such as Acquisition, Analysis, or Printing, could not enter the configuration menu.*

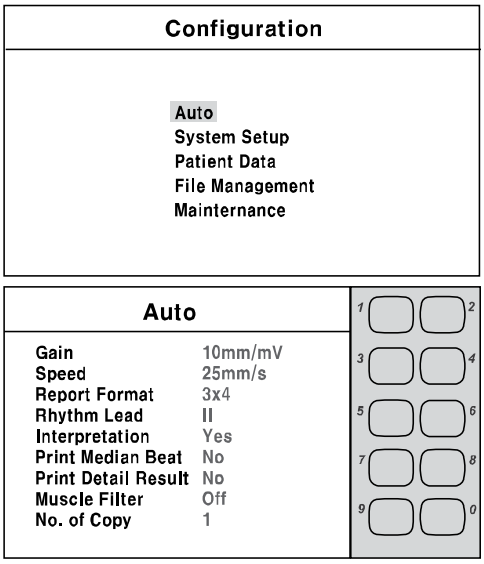


Figure 3-5 Automatic mode configuration

3) **The parameter list of Automatic configuration.**

Gain(mm/mV) 5, 10, 20
Speed(mm/s) 5, 10, 25, 50
Report Format 2x6, 3x4, 2+R, 3+R, 6x2
Rhythm Lead I, II, III, aVR, aVL, aVF, V1, V2, V3, V4 V5, V6
Interpretation Yes, No
Print Median Beat Yes, No
Print Detail Result Yes, No
Muscle Filter 25Hz, 35Hz, Off
No. of Copy 0, 1, 2, 3, 4, 5, 6, 7, 8, 9

Gain Select the input gain rate. Selectable options are 5, 10 or 20mm/mV
**If the report format is selected as 6x2, the gain is fixed as 5mm/mV.*

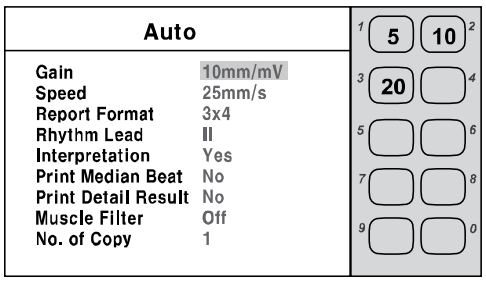


Figure 3-6 Gain (Automatic mode)

Speed Select the paper speed. Selectable options are 5, 10, 25 or 50mm/s.
**If the report format is selected as 6x2, the speed is fixed as 25mm/s.*

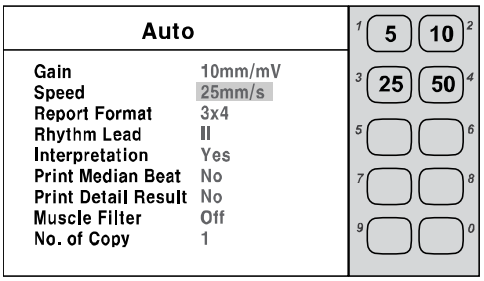


Figure 3-7 Speed (Automatic mode)

Tip	
1 Gain	If press the **Gain** button at Home Screen, it will be switched input gain among 5, 10, and 20mm/mV without enter the configuration menu.
2 Speed	If press the **Speed** button at Home Screen, it will be switched print speed among 5, 10, 25, 50 mm/s without enter the configuration menu.

Report format The YM303i has 5 different styles of report formats. The report styles are identified by ECG waveform matrix. The automatic report includes interpretation result and detail result.
**Display format and Print format are independent at Automatic mode.*

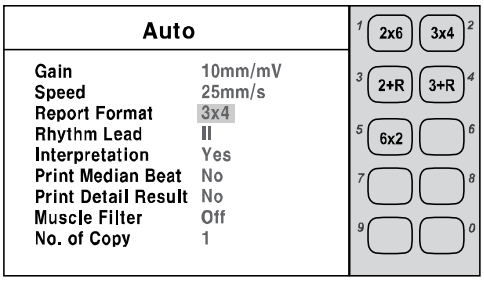


Figure 3-8 Report format (Automatic mode)

2x6 12 Lead ECG waveform prints in 2x6

Figure 3-9 Format 2x6

3x4 12 Lead ECG waveform prints in 3x4

Figure 3-10 Format 3x4

2+R 12 Lead ECG waveform prints in 2x6 and a rhythm lead added

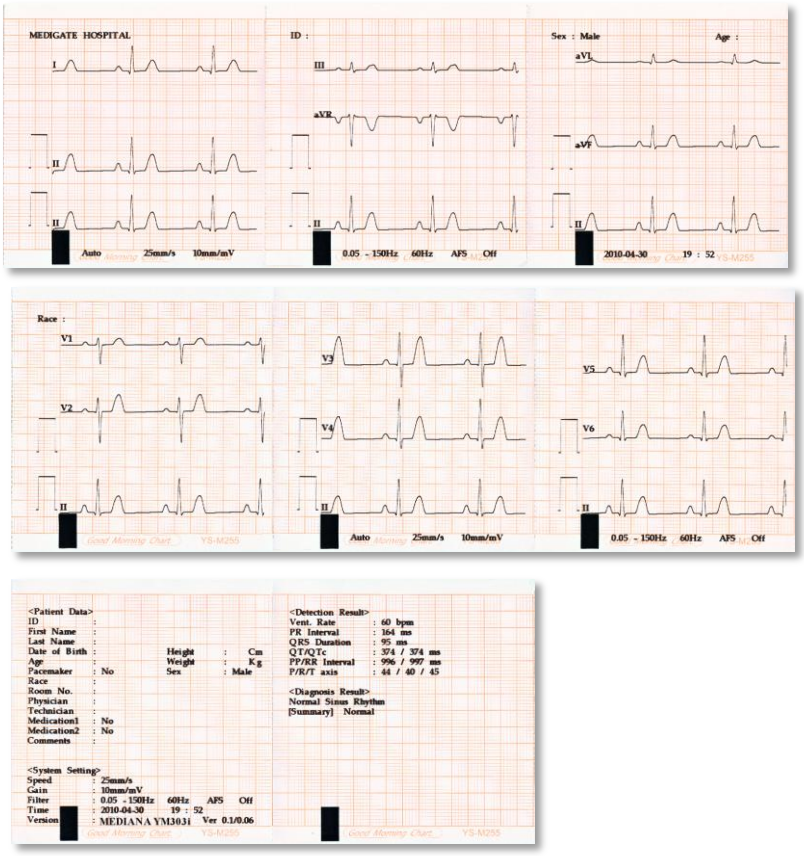


Figure 3-11 Format 2+R

3+R 12 Lead ECG waveform prints in 3x4 and a rhythm lead added.

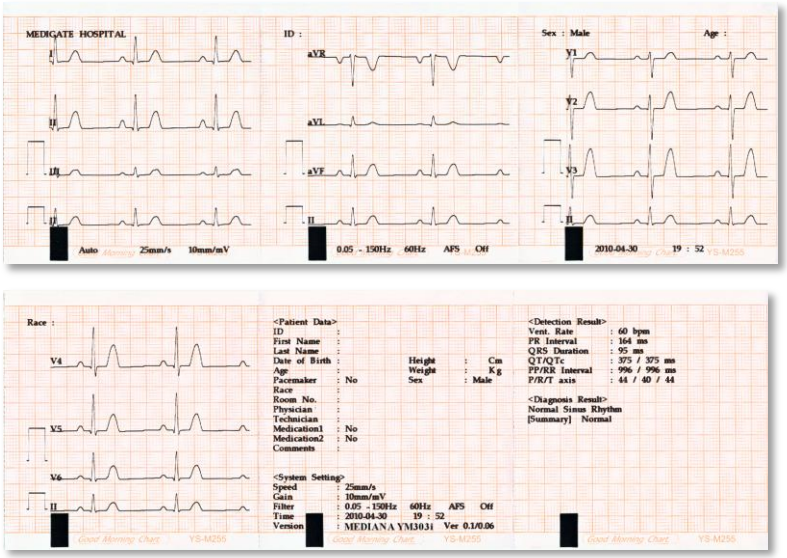


Figure 3-12 Format 3+R

6x2 12 Lead ECG waveform prints in 6x2

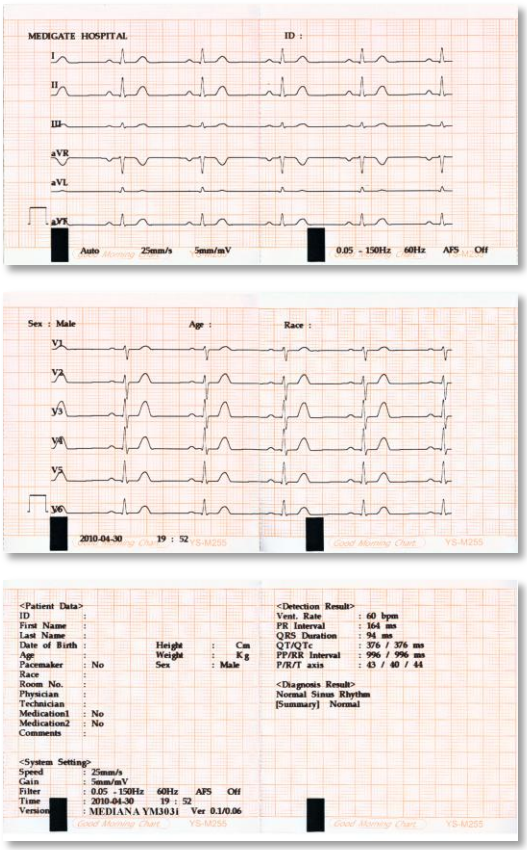


Figure 3-13 Format 6x2

Rhythm Lead

This parameter is applied for format 2+R and 3+R. The rhythm lead is selected with the keypad. The figure 3–14 shows selective options if you want go next page press the **right(▶)** button and back for the **left(◀)** button.

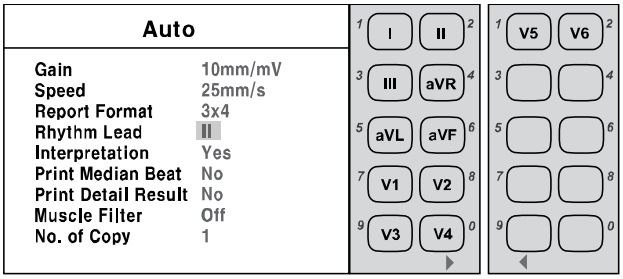


Figure 3-14 Rhythm lead select (Automatic mode)

Interpretation This option selects the interpretation report print or not. Yes for print, No for not print interpretation result.

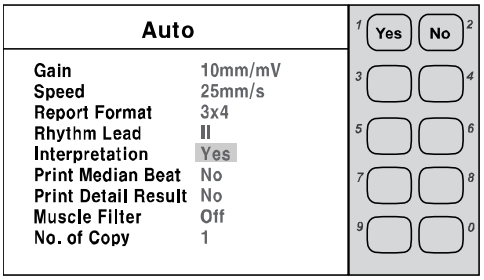


Figure 3-15 Interpretation print

Print Median Beat Median Beat print option.
**This option works when the 'Interpretation' option set to 'Yes'.*

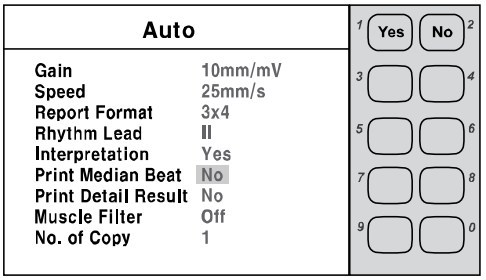


Figure 3-16 Median Beat print

Print Detail Result Detail result print option

**This option works when the 'Interpretation' and 'Print Median Beat' options set to 'Yes'.*

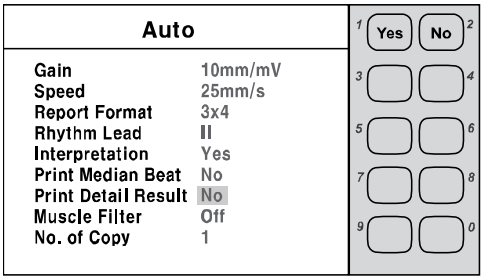


Figure 3-17 Detail result print

Muscle Filter The muscle filter select

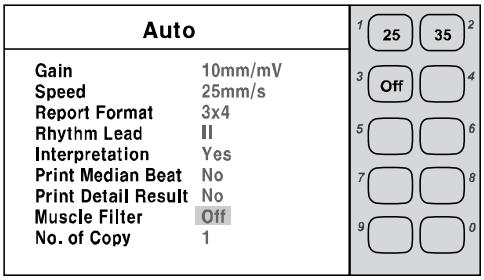


Figure 3-18 Muscle Filter select

Tip
3 Filter — If press the **Filter** button at home screen, filter adjust window will be opened.

No. of Copy This option is select how many extra copies will be printed.
The '〈Copy Print〉' mark will be located on the first page of extra report(s).

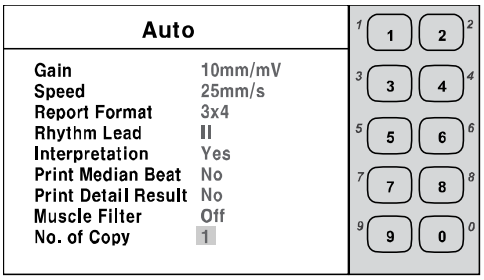


Figure 3-19 No. of Copy set

Tip
8 Copy — If press the **Copy** button at home screen, last printed report will be printed. *Automatic mode only. If power off the device, last printed report in memory will be lost.

2.3.2 Manual mode Menu

1) Switch to Manual mode

Press the **MANUAL** button for switch to manual operation mode. All parameter of manual mode is changed only at manual mode.

2) Press the MENU button to enter the configuration menu.

Press the **MENU** button for configuration menu and move the cursor on **Manual** and press the **ENTER** button.

*It is impossible to enter the configuration menu during other function operate such as report printing or ECG acquisition.

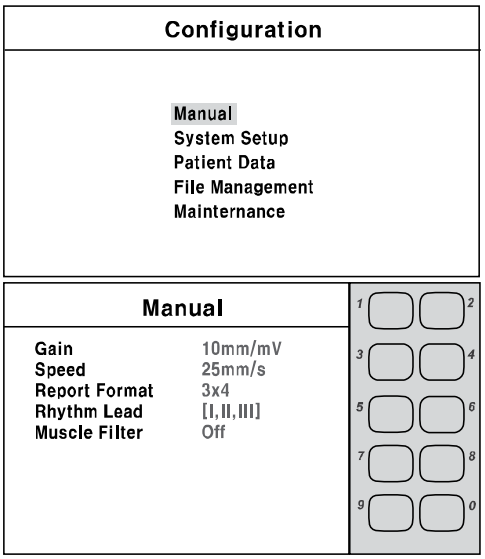


Figure 3-20 Manual mode setting

3) The parameters of Manual mode

Gain(mm/mV) 5, 10, 20
Speed(mm/s) 5, 10, 25, 50
Report Format M1R, M2R, M3R, M6R
Rhythm Lead
M1R : [I], [II],[III], [aVR], [aVL], [aVF], [V1], [V2], [V3], [V4], [V5], [V6]
M2R : [I,II], [III, aVR], [aVL, aVF], [V1, V2], [V3, V4], [V5, V6], Custom Lead
M3R : [I,II,III], [aVR, aVL, aVF], [V1, V2, V3], [V4, V5, V6], Custom Lead
M6R : [I, II, III, aVR, aVL, aVF], [V1, V2, V3, V4, V5, V6]
Muscle Filter 25Hz, 35Hz, Off

Gain This parameter sets the input gain. If the gain value is big, height of ECG signal will be tall.

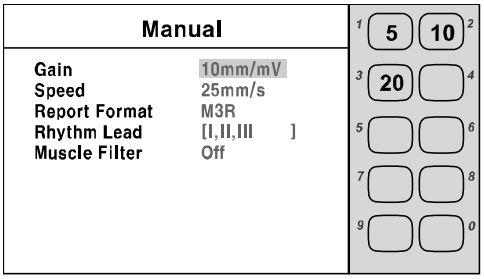


Figure 3-21 Gain setting (Manual mode)

Speed This parameter sets the paper speed. If the speed value is big, print speed will be fast.

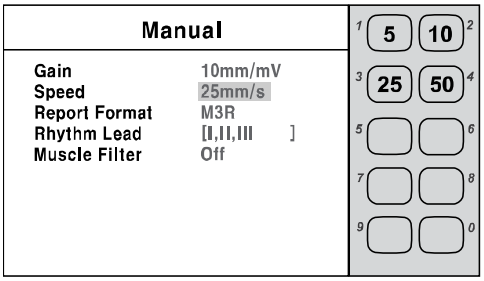


Figure 3-22 Speed set(Manual mode)

Tip	
1 Gain	If press the **Gain** button at Home Screen, it will be switched input gain among 5, 10, and 20mm/mV without enter the configuration menu.
2 Speed	If press the **Speed** button at Home Screen, it will be switched print speed among 5, 10, 25, 50 mm/s without enter the configuration menu.

Report format The manual operation mode has 4 types report formats, it is selected using keypad.

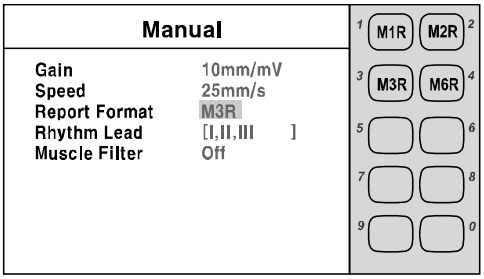


Figure 3-23 Report format(Manual mode)

M1R This format is printed 1 rhythm lead.

Figure 3-24 Format M1R

M2R This format is printed 2 rhythm leads.

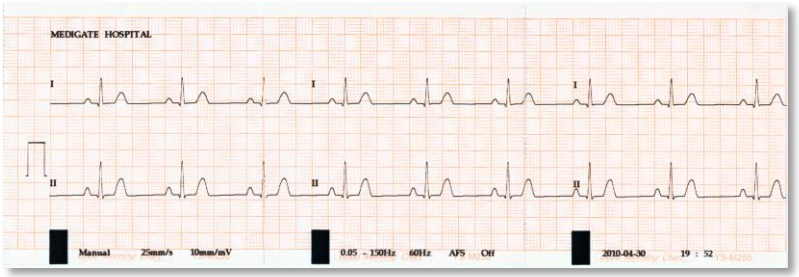


Figure 3-25 Format M2R

M3R This format is printed 3 rhythm leads.

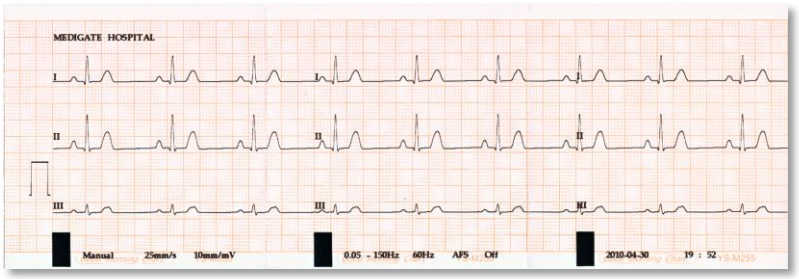


Figure 3-26 Format M3R

M6R This format is printed 6 rhythm leads.

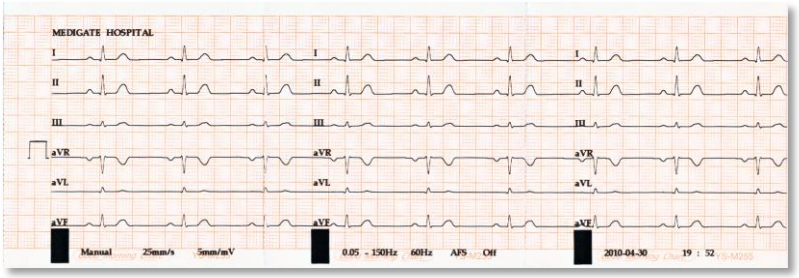


Figure 3-27 Format M6R

Rhythm Lead This menu applied on the report format. There are some options of rhythm lead.

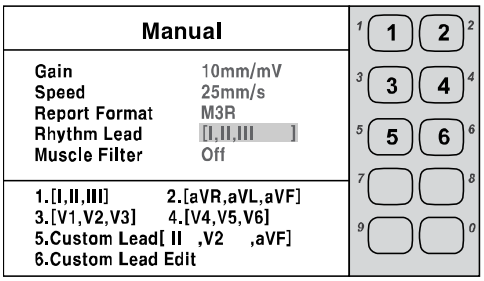


Figure 3-28 Rhythm lead select

Muscle Filter The muscle filter is reducing noise from muscles.

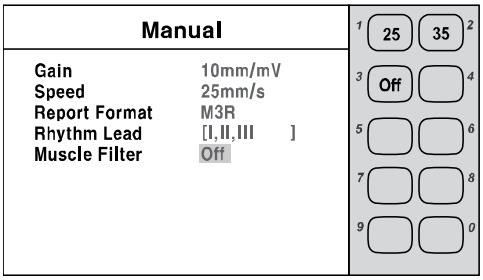


Figure 3-29 Muscle Filter select

Tip	
3 Filter	If press the **Filter** button at home screen, filter adjust window will be opened.

3.3.3 System Setup Menu

1) Press the MENU button to enter the configuration menu.

If press the **MENU** button at Home-Screen, it will be shown the Configuration menu. Move the cursor on **System setup** and press the **ENTER** button to enter the submenu of Auto configuration.

**If other function is running such as Acquisition, Analysis, or Printing, could not enter the configuration menu.*

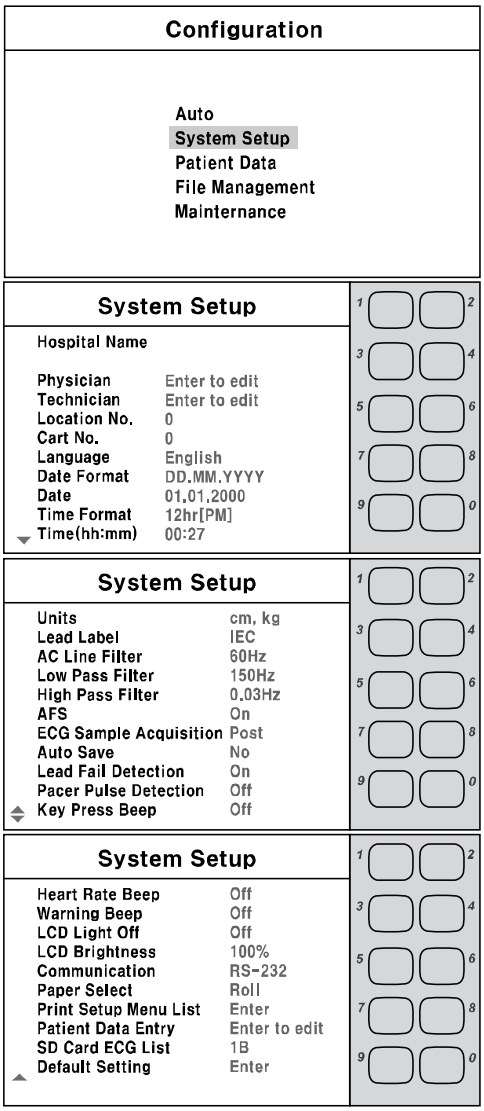


Figure 3-30 System configurations

The System Setup has 3pages of parameters. The triangle(▲) and inverted triangle (▼)mark left side of parameter list means more page exist. Press the up or down cursor button to move to parameter. These parameters are applied on Automatic mode and Manual mode both. Selectable items blow.

Hospital name A-Z(20 characters)
Physician A-Z(9 characters)
Technician A-Z(9 characters)
Location No. 0-9(3 digits)
Cart No. 0-9(3 digits)
Language English, Español, Italiano, Indonesian, Język Pols
Date format DD.MM.YYYY, MM/DD/YYYY, YYYY-MM-DD
Date
Time format 12hr, 24hr
Time(hh:mm)
Units cm kg , in lb
Lead Label IEC, AAMI
AC Line filter(Hz) 60, 50, off
High Pass filter(Hz) 0.04, 0.05, 0.1, 0.16, 0.3
Low Pass filter(Hz) 40, 100, 150, off
AFS On, Off
ECG Sample Acquisition Pre, Post
Auto Save On, Off
Lead Fail Detection On, Off
Pacer Pulse Detection On, Off
Key Press Beep On, Off
Warning Beep On, Off
Heart Rate Beep On, Off
LCD Light off(min) Off, 1, 3, 5, 10, 30
LCD Brightness(%) 20, 40, 60, 80, 100
Communication RS-232, TCP/IP
Paper Select Z-fold, Roll
Print Setup Menu List
Patient Data Entry
SD Card ECG List 1P, 1B
Default Setting Enter

Hospital Name Enter the name of hospital using number pad.
Alphabets are assigned to number pad. The left(◀) or right(▶) cursor button for shift other alphabets.

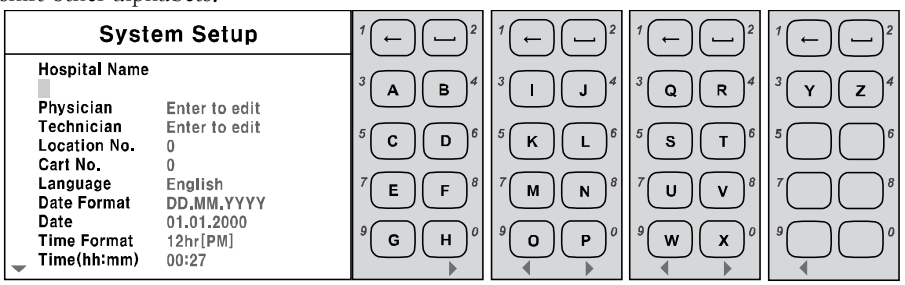


Figure 3-31 Hospital Name

Physician Insert new physician or edit listed physician. Listed physicians will be used 〈Patient Data〉 section of report. Move the cursor on **Physician** item and press the **ENTER** button to enter the physician edit menu. There are 8 physicians are available to list.

Write or Modify

Move the cursor to **Select** column using the left(◀) or right(▶) cursor button. Press the number of list to write or modify using number pad and press the **ENTER** button. It will move to the line of select and type the first name and last name. First name and last name section is switched with the left(◀) or right(▶) cursor button.

Delete

Move the cursor to **Delete** column using the left(◀) or right(▶) cursor button. Press the number of list to delete using number pad and press the **ENTER** button. It will be deleted.

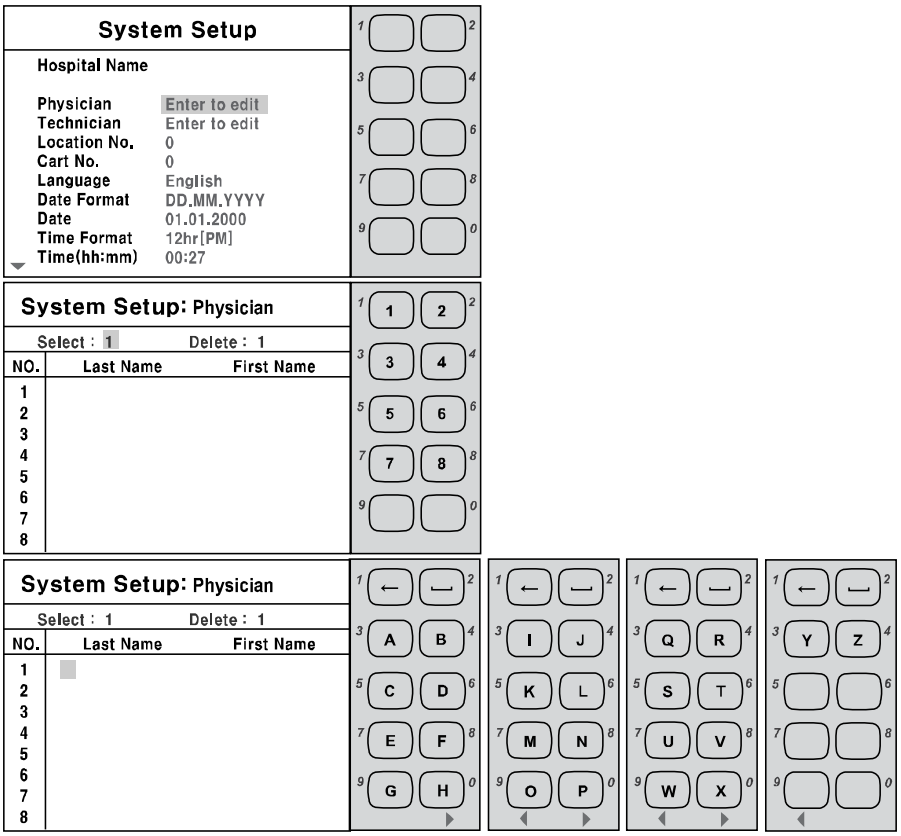

System Setup
Hospital Name
Physician Enter to edit
Technician Enter to edit
Location No. 0
Cart No. 0
Language English
Date Format DD.MM.YYYY
Date 01.01.2000
Time Format 12hr[PM]
Time(hh:mm) 00:27
System Setup: Physician
Select : 1 Delete : 1
NO. Last Name First Name
1 2 3 4 5 6 7 8
System Setup: Physician
Select : 1 Delete : 1
NO. Last Name First Name
A B C D E F G H
I J K L M N O P
Q R S T U V W X
Y Z

Figure 3-32 Physician List edit

Technician Insert new technician or edit listed technician. Listed technician will be used 〈Patient Data〉 section of report. Move the cursor on **Technician** item and press the **ENTER** button to enter the technician edit menu. There are 8 technician are available to list.

Write or Modify

Move the cursor to **Select** column using the left(◀) or right(▶) cursor button. Press the number of list to write or modify using number pad and press the **ENTER** button. It will move to the line of select and type the first name and last name. First name and last name section is switched with the left(◀) or right(▶) cursor button.

Delete

Move the cursor to **Delete** column using the left(◀) or right(▶) cursor button. Press the number of list to delete using number pad and press the **ENTER** button. It will be deleted.

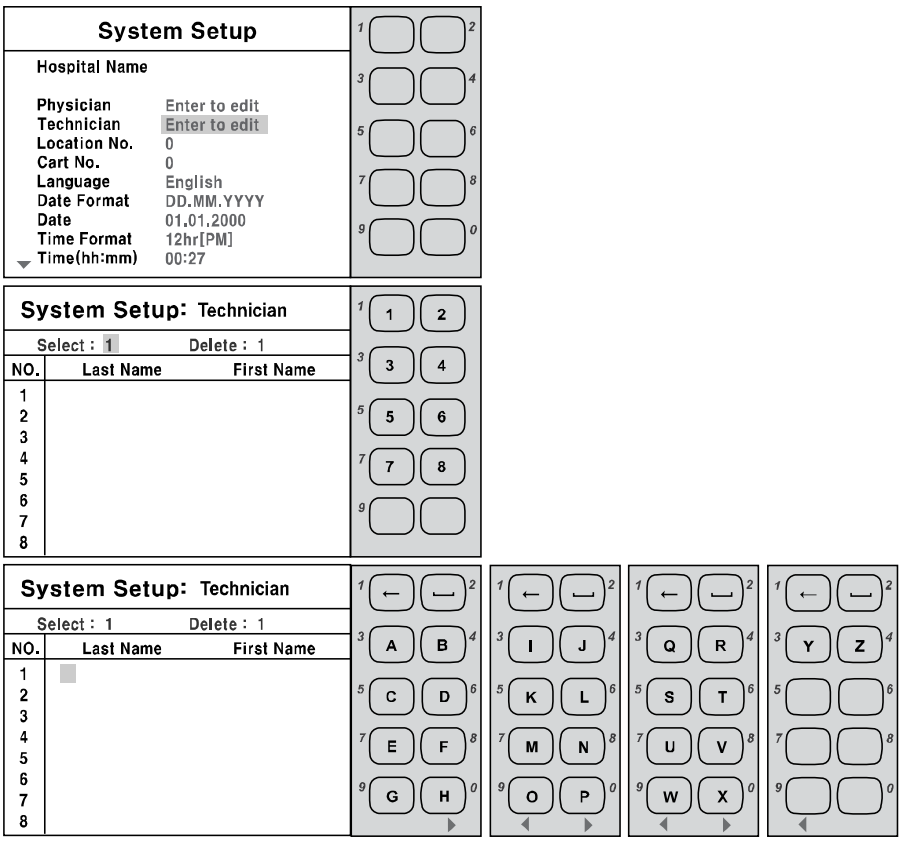

System Setup
Hospital Name
Physician Enter to edit
Technician Enter to edit
Location No. 0
Cart No. 0
Language English
Date Format DD.MM.YYYY
Date 01.01.2000
Time Format 12hr[PM]
Time(hh:mm) 00:27
System Setup: Technician
Select : 1 Delete : 1
NO. Last Name First Name
1 2 3 4 5 6 7 8
System Setup: Technician
Select : 1 Delete : 1
NO. Last Name First Name
1 2 3 4 5 6 7 8
A B C D E F G H
I J K L M N O P
Q R S T U V W X
Y Z

Figure 3-33 Technician List edit

Location No. When using multiple devices from multiple locations, each device can be assigned a location number.

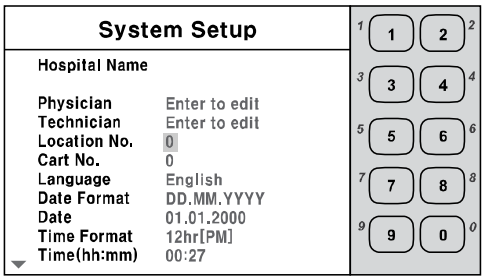


Figure 3-34 Location Number

Cart No. When using multiple devices from multiple carts, each device can be assigned a cart number.

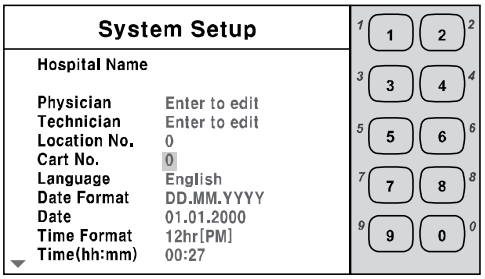


Figure 3-35 Cart Number

Language When the cursor moved on **Language** parameter and press the **ENTER** button it, will be shown up the selection box. Set the desired language with number pad.

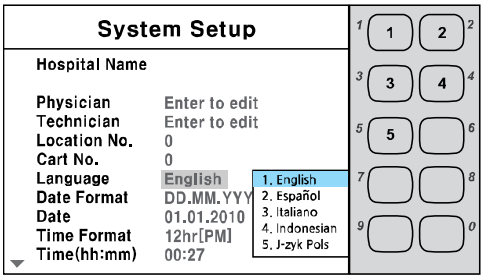


Figure 3-36 Language Set

Date format When the cursor moved on **Date Format** parameter and press the **ENTER** button, it will be shown up the selection box. Set the desired date format with number pad.

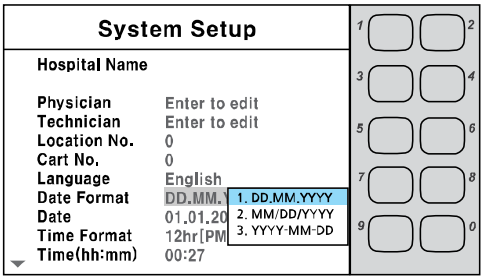


Figure 3-37 Data format setting

Date Move the cursor on **Date** field and set the current date with number pad.

Example〉 If today is 2010-08-26 and date format is yyyy-mm-dd,

Then type the flowing numbers using number pad

[Type] 2, 0, 1, 0, 0, 8, 2, 6

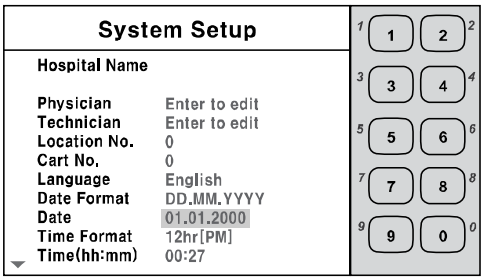


Figure 3-38 Date setting

Time format Move the cursor on **Time Format** field and set the desired time format with number pad.

Example1〉 If current time is 2:30pm and desired time format is [12h]

Then type the flowing numbers using number pad.

[Type] 1, 4

Example2〉 If current time is 2:30pm and desired time format is [24h]

Then type the flowing numbers using number pad.

[Type] 2

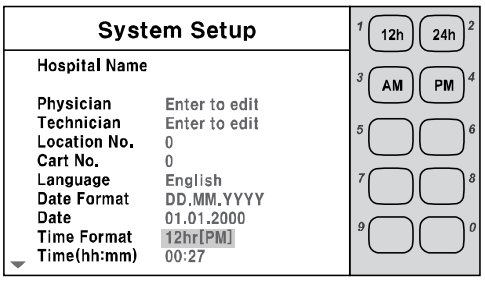


Figure 3-39 Time format select

Time Move the cursor on **Time** field and set the current time with number pad.

Example1〉 If current time is 2:30pm and desired time format is [12h]

Then type the flowing numbers using number pad.

[Type] 0, 2, 3, 0

Example2〉 If current time is 2:30pm and desired time format is [24h]

Then type the flowing numbers using number pad.

[Type] 1, 4, 3, 0

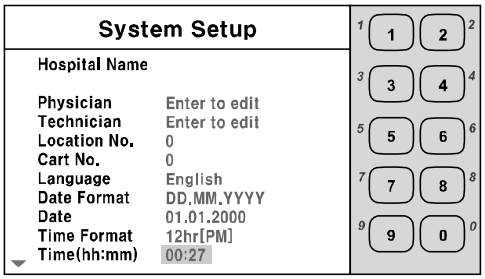


Figure 3-40 Time set

Units Move the cursor on **Units** field and select desire units.

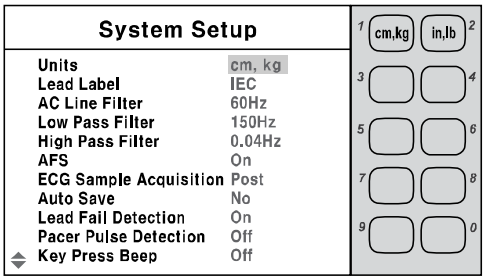


Figure 3-41 Units select

Lead Label Move the cursor on **Lead Label** field and select desire labels.

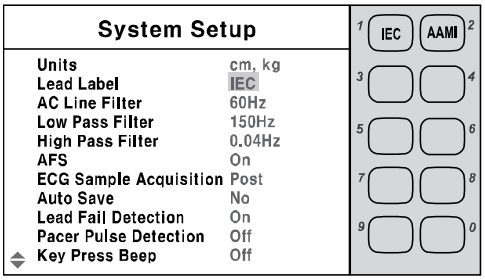


Figure 3-42 Lead label select

AC Line filter Select the AC line filters. Set the AC line filter to your local AC power line rating.(50Hz or 60Hz)

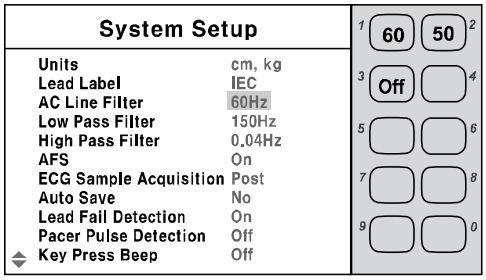


Figure 3-43 AC Line filter select

High Pass filter Select cutoff frequency of the high pass filter.

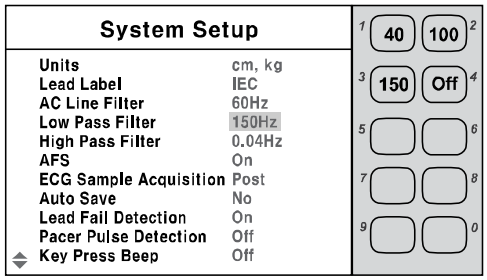


Figure 3-44 High Pass Filter select

Low Pass filter Select cutoff frequency of the low pass filter.

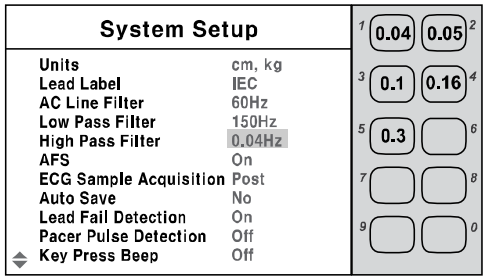


Figure 3-45 Low Pass Filter select

Tip
3 Filter — Press the **Filter** button to adjust high pass filer and low pass filter at the home screen.

AFS AFS stand for Anti-Floating System. The AFS reduce wondering or drifting on base line.

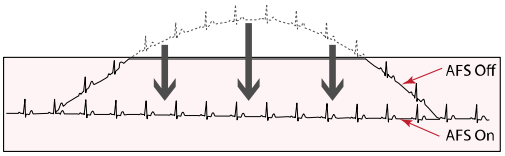


Figure 3-46 Anti-Floating System

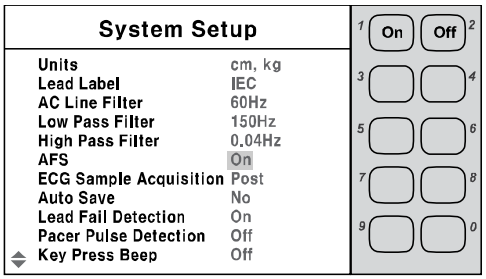


Figure 3-47 AFS Setting

ECG Sample Acquisition This parameter is selecting the timing of ECG signal acquisition beginning.

Pre-sample mode

If this parameter set to **PRE**, the pre-sampling buffer is enabled. It means a report created with the ECG data acquitted before the **RUN** button pressed.

Post-sample mode

If this parameter set to **POST**, the pre-sampling buffer is disabled. It means a report created with the ECG data acquitted after the **RUN** button pressed.

**This parameter applies to only Automatic mode.*

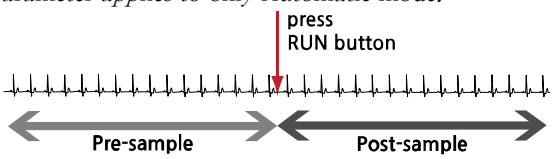


Figure 3-48 Pre-sample vs. Post-sample

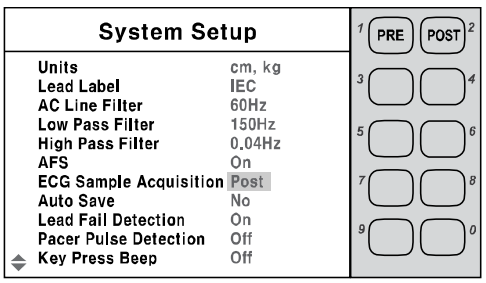


Figure 3-49 Pre-sample vs. Post-sample

Auto Save If this parameter set to Yes, the device automatically saves the ECG data at internal or external (option) memory every record.

**This parameter applies to only Automatic mode.*

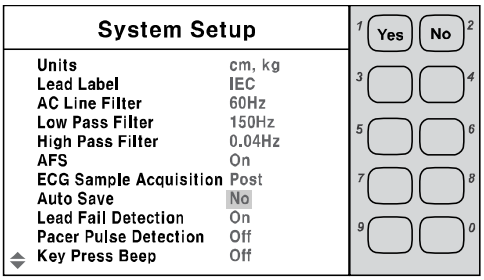


Figure 3-50 Auto Save

Lead Fail Detection This function is detecting lead fail situation. It means bad connection the device and the patient occurred. If lead fail is detect it will be shown at the home screen of Lead fail indication section. *(see the Home Screen, p26)*

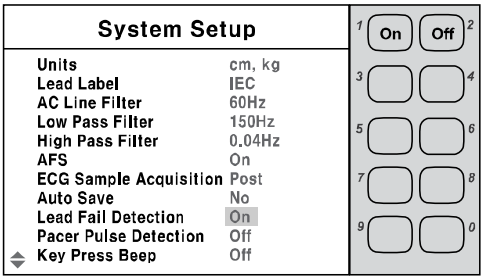


Figure 3-51 Lead Fail Detection

Pacer Pulse Detection If this parameter set to on pacemaker detecting mark printed with reports.

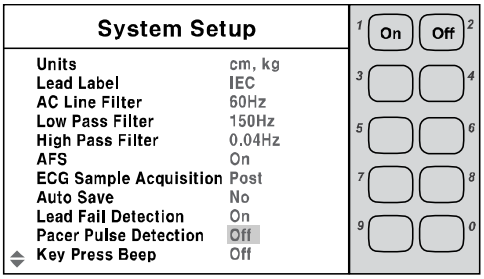


Figure 3-52 Pacemaker Detector

Key Press Beep If this option set to on the device will make a beep sound when a key pressed.

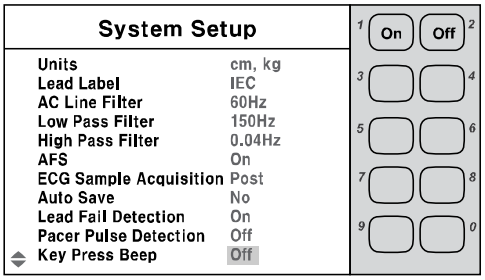


Figure 3-53 Key Press Beep On

Heart Rate Beep If this operation set to on the device will make a beep sound when heart a peak detected.

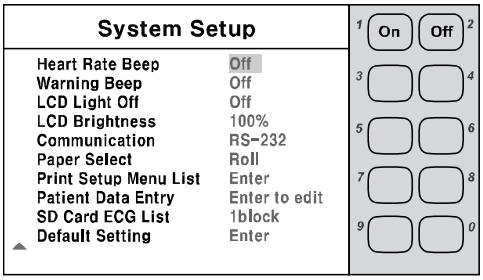


Figure 3-54 Heart Rate Beep On

Warning Beep If this operation set to on the device will make a beep sound when warning situation occurred.

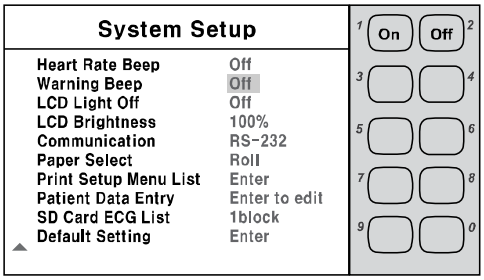


Figure 3-55 Warning Beep On

LCD Light off This parameter sets back light off time of LCD for saving battery. If the 5 is selected, the device will be turned off the back light when no button pressed within 5 minutes.

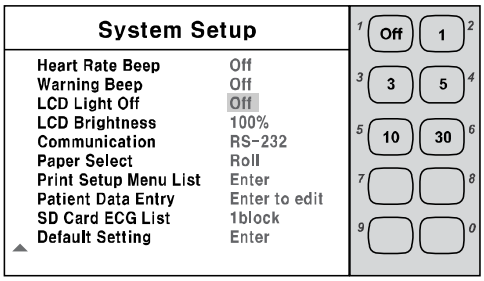


Figure 3-56 LCD Backlight off time set

LCD Brightness This parameter is adjusting brightness of LCD.

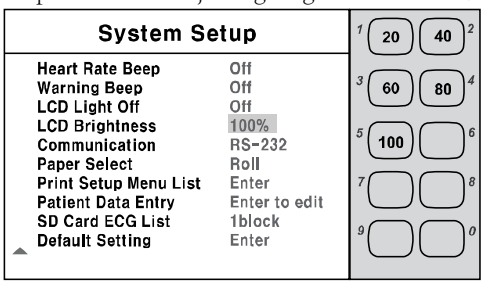


Figure 3-57 LCD Brightness adjust

Communication This parameter is selecting communication port, 232 for RS-232(serial port) and TCP for TCP/IP(LAN port)

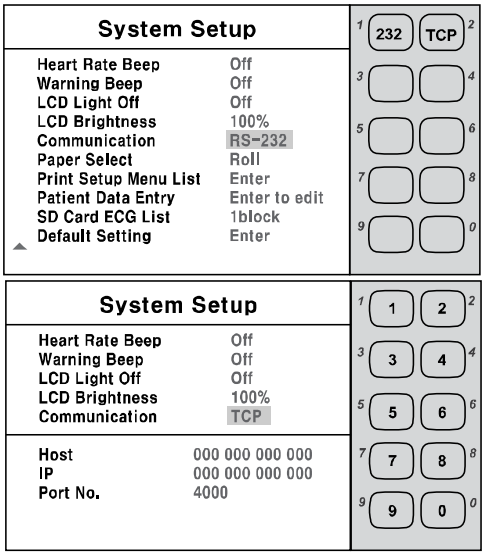


Figure 3-58 Communication port select

Paper Select This parameter is selecting the loaded paper type, Z for z-fold type paper and R for Roll type paper.

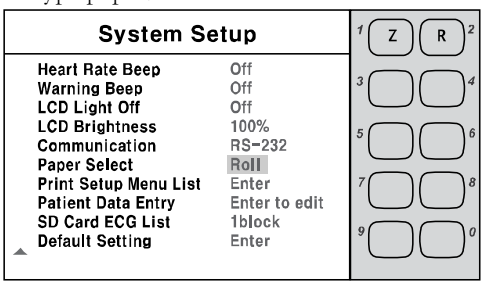


Figure 3-59 Paper type set

Print Setup Menu List If the cursor move to this filed and press the ENTER button the device will print all setting value.

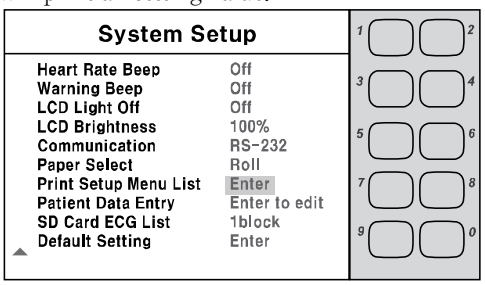


Figure 3-60 Print Setup Menu List

Patient Data Entry The device prints the patient data in the report.

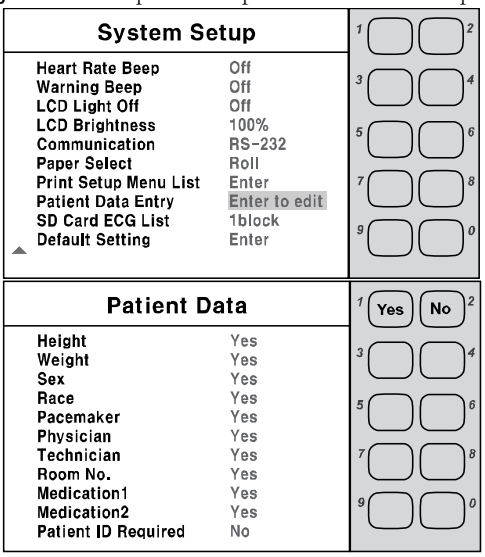


Figure 3-61 Patient Data Entry Edit

SD Card ECG List This parameter selects printing area of stored ECG list in SD card.

1P: The most recent page will be printed.

1B: 1block(100 EA) of list form selected data will be printed.

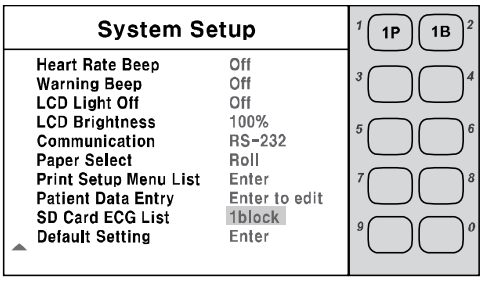


Figure 3-62 SD Card ECG List print set

Default Setting If use this option the device will changes to its original settings by manufacture.

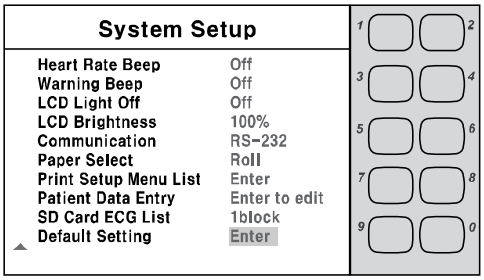


Figure 3-63 Default Setting

Auto mode	
Gain(mm/mV)	10
Speed(mm/s)	25
Report Format	3x4
Rhythm Lead	II
Interpretation	Yes
Print Median Beat	No
Print Detail Result	No
Muscle Filter	Off
No. of Copy	1

Manual mode	
Gain(mm/mV)	10
Speed(mm/s)	25
Report Format	M3R
Rhythm Lead	M3R：[I,II,III]
Muscle Filter	Off

Patient data	
Patient ID	Blank
Last name	Blank
Fist name	Blank
Date of birth	00.00.0000
Sex	male
Height	0
Weight	0
Race	No
Pacemaker	No
Physician	Blank
Technician	Blank
Room No.	0
Medication1	No
Medication2	No
Comment1	Blank
Comment2	Blank

System setup	
Hospital name	Blank
Physician	Blank
Technician	Blank
Location No.	0
Cart No.	0
Language	English
Date format	DD.MM.YYYY
Date	unchanged
Time format	12hr
Time(hh:mm)	unchanged
Units	cm,kg
Lead Label	IEC
AC Line Filter(Hz)	location dependent
Low Pass Filter(Hz)	150
High Pass Filter(Hz)	0.05
AFS	On
ECG Sample Acquisition	Post
Auto Save	No
Lead fail Detection	On
Pace Pulse Detection	Off
Key Press Beep	Off
Warning Beep	On
Heart Rate Beep	Off
LCD Light off(min)	20
LCD Brightness(%)	100
Communication	RS-232
Paper Select	Roll
Patient Data Entry	
Patient ID Required: No, The Others: Yes	
SD Card ECG List	1block

3.3.4 Patient Data Menu

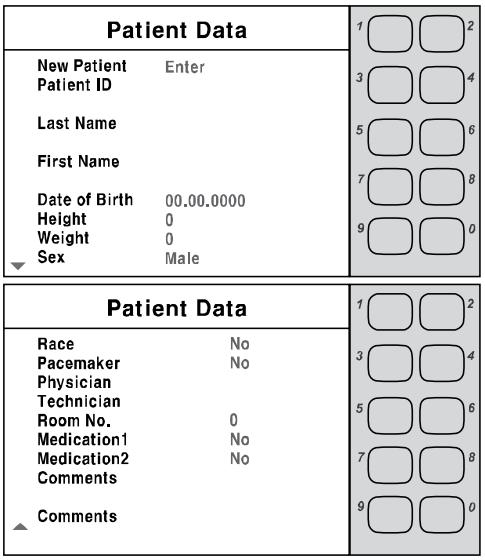


Figure 3-64 Patient Data editor

The patient data menu is made for note the patient information. This information will be printed on the report and saved with ECG data when save button pressed or automatically saved at the Auto save mode.

New patient Yes, No
Patient ID 0~9(20 characters)
Last name A~Z(20 characters)
Fist name A~Z(20 characters)
Date of birth
Sex male, female
Height 0~9(3 digits)
Weight 0~9(3 digits)
Race No, Caucasian, black, Asian, oriental, Hispanic, native American, pacific Island, Hawaiian, Mongolian
Pacemaker Yes, No
Physician
Technician
Room No. 0~9(4 digits)
Medication1 No, digitalis, diuretics, antidepress, steroids, nitrtes, ace, cytostatics
Medication2 No, digitalis, diuretics, antidepress, steroids, nitrtes, ace, cytostatics
Comment1 A~Z(20 characters)
Comment2 A~Z(20 characters)

Tip

If the **PATIENT** button is pressed at home screen, it will be enter the menu for patient data edit.

3.3.5 File Management Menu

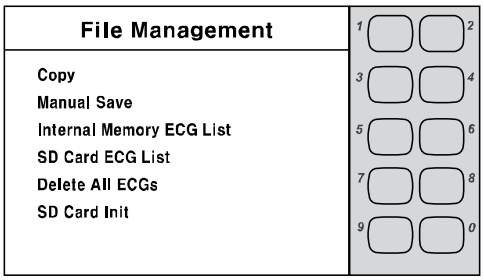


Figure 3-65 File Management menu

Stored data are could be management at this menu.

Copy Extra report printing of last recorded ECG at automatic mode.

Manual save Save the last recorded ECG at automatic mode manually

Internal memory ECG list Show the list of ECGs recorded in internal memory

SD Card ECG list Show the list of ECGs recorded in SD card

Delete All ECGs Delete all ECGs recorded in internal memory and SD card

SD Card ECG Init Initialize a SD card

*Before using a new SD card must be initialized

3.3.6 Maintenance Menu

There are menus for operation testing of the device. Bellow items available.

Demonstration mode	**LAN test**
LCD test	**SD card test**
Buzzer test	**USB test**
Keypad test	**Patient cable test**
Thermal print test	**ECG acquisition module test**
RS232 test	**Print test result summary**

For more detail information, please refer to

Chapter4. Device Maintenance > 4.6 Maintenance Menu

Chapter4.

Device Maintenance

Chapter4. Device Maintenance

4.1 Loading Printer Paper

Roll type and z-fold type paper can be used on the YM303i. Figure 4-1 shows ending mark of roll and Z-fold type paper. Ending mark is located back side of roll type paper and front side of z-fold type paper. If ending mark shows up reload new paper.

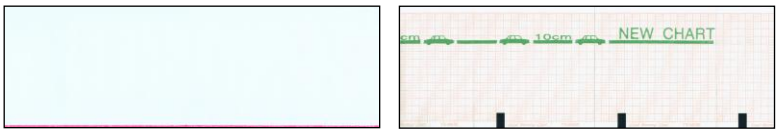
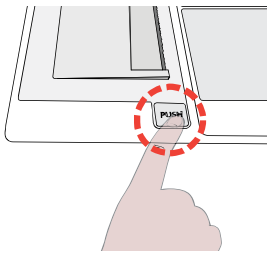
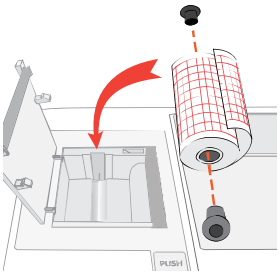


Figure 4-1. The paper ending mark (left: Roll type, right: Z-fold type)
NOTE: Ending mark of the paper could be changed without notice.

4.1.1 Roll type paper loading

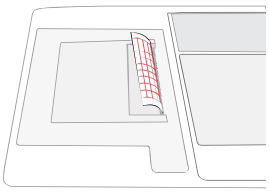


1) Press the PUSH button to open the paper compartment.



2) Put the 'shaft' into grad of roll-type paper and insert it to paper container by following the shaft guide.

NOTE: The shafts are not for single use, do not throw it away.

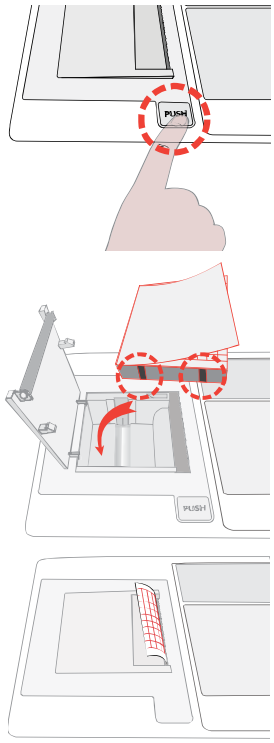


3) Release the paper and must be positioned exactly on the cover roller, before the cover is closed.

NOTE: Check the paper type at the device.

Figure 4-2. Roll type paper loading

4.1.2 Z-fold type paper loading



1) Press the PUSH button to open the paper compartment.

2) Put the Z-fold paper to the paper container. If roll paper guide is remained remove it. The black maker is lower side.

NOTE: The shafts are not for single use, do not throw it away.

3) Fold out the first page of paper to the right and close the cover.

NOTE: Check the paper type at the device.

Figure 4-3. Z-fold type paper loading

Caution: Use only MEDIANA Co., Ltd. supplied paper. If use other products it may make poor quality printing or damage on the device.

4.2 Cleaning

Warning: Shock Hazard

- Unplug the AC power cord from AC outlet before the device cleaning or disinfecting its surface.
- Do not spray, pour, or spill any liquid directly to the device for cleaning or disinfection.
- If cleaning liquid enters into the device, unplug the power cord and contact to the service center.
- When cleaning or disinfecting surface of the device or electrode, fully dry and use it.

Caution:

- When cleaning the equipment, wipe it with sponge or something like that wetted with soapy water and never use the detergent using alcohol, ammonia or acetone as main ingredient.

4.2.1 Cleaning the device

1) Unplug the AC power cord from AC outlet.
2) Do not spray to the device directly, instead cleaning with soft moist cloth.
3) Dry enough before use the device.

4.2.2 Cleaning patient cable

1) Disconnect the cable from the device before cleaning or disinfecting it. When disconnecting the cable, be sure to pull on the connector, not on the cable.
2) Clean the cable by rubbing it down with a cloth moistened with soap water. Use a disinfectant for disinfection. Do not immerse the cable in liquid.

4.2.3 Cleaning electrodes

1) Clean reusable electrodes immediately after using it.
2) Peel off the adhesive foil before cleaning the electrodes (rests of the adhesive can be removed with benzene).
3) Then use warm water and a small brush to clean the electrodes of cream or gel. Do not use pointed or sharp objects for cleaning.
4) Disinfect the electrodes with alcohol-free disinfectant. Ensure that connectors and sockets do not become wet.

4.2.4 Cleaning the printer head

1) Unclean printer head can be cause of reducing print quality.
2) Open the printer cover and then wipe it softly without rubbing it too hard by wetting swab with 90% alcohol.
3) After cleaning, dry printer head sufficiently and then use it.

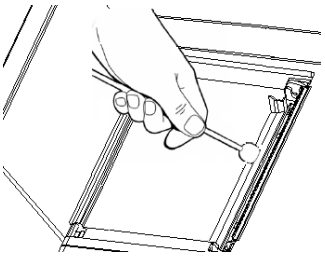


Figure 4-4. Cleaning the printer head

4.3 Storing

4.3.1 Storing thermal paper

1) Store the paper in suitable rooms at a temperature between 18℃ and 24℃ (65˚F and 75˚F)and relative humidity between 40% and 60%
2) Avoid direct contact of the paper with
-carbon and carbonless forms
-chat papers and adhesives containing tributly phosphate, dibutyl phthalate, or any other organic solvents
-document protectors, envelopes, and sheet separators containing plasticizers
-solvents or solvent-based products containing alcohols, ketones, esters, or other substances from this chemical group
3) Printout paper discoloration may occur at unsuitable environment (temperature, humidity or period (with in 1 year)).

4.4 Checklist before using the YM303i

Following list is needed to visual check before every using the YM303i for your safety.

Did the device get any physical damage on surface?
Did the device get wet?
Did the AC cable get any physical damage?
Did the patient cable get any physical damage?
Is the safety labels attached on right place?

Warning: Approved user only

- Some menu of the **Maintenance Menu** is need electrical knowledge and technic. It may cause hazard user and device.

4.5 Maintenance Menu

The YM303i has Maintenance Menu. It is provide testing functions, demonstration, and system information.

1) Press the **MENU** button to enter the Configuration menu.

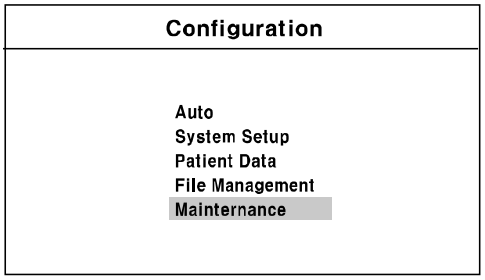


Figure 4-5. Enter to the Maintenance Menu

2) Move the cursor on the Maintenance and press the **ENTER** button. When password prompt shows up, enter the code '3031'.

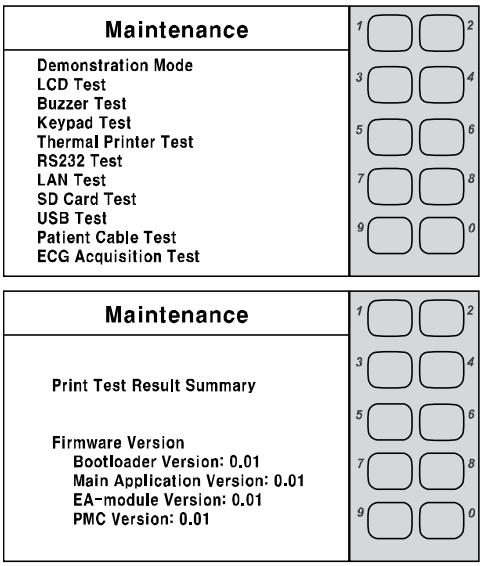


Figure 4-6. Maintenance Menu

4.5.1 Demonstration Mode

If Demonstration mode is enabled ECG signal displays on the LCD with out signal source.

4.5.2 LCD Test

LCD test menu is useful to find some LCD problems. If you found some problems using this menu, contact to the service center.

Figure 4-7. LCD Test

4.5.3 Buzzer Test

Buzzer test is provided to check sound warning signal. When buzzer test is started you can hear 4 times beep sound.

4.5.4 Keypad Test

Keypad test is provided to check the button of YM303i. When the test is started red outline shows up on a target button. If the target button is not pressed the test will be finished.

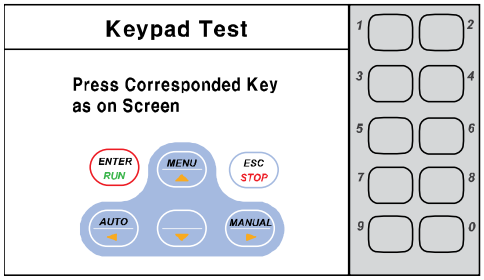


Figure 4-8 Keypad Test

4.5.5 Thermal Printer Test

Thermal printer test is provided to check the thermal printer module. At this test the print test pattern will be printed. If printing quality is not good cleaning the printer head. Printing quality is not improved after cleaning, please contact to service center.

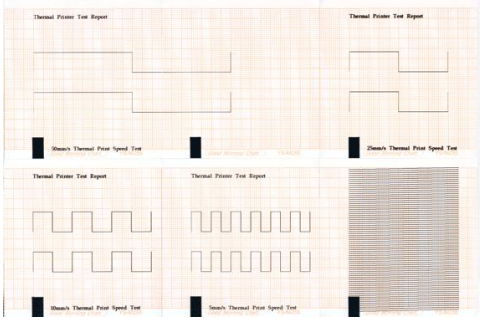


Figure 4-9 Thermal Printer Test

4.5.6 RS232 Test

Warning: Electrical shock hazard

- Avoid enter electrically conductive object, such as metal clip, metal wire, or staples, inside of device. Do not contact metal part of case except RS232 port with electrically conductive object when the device is operating it may cause electrical shock hazard.

The RS232 test is provided to check the RS232 communication module. Before this testing pin 2 and 3 are should be shorted. Figure 4-10 shows pin layout of device.

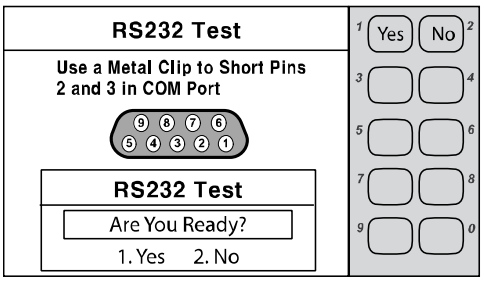


Figure 4-10 RS232 Test

4.5.7 LAN Test

This test is provided for the TCP/IP module(option) testing.

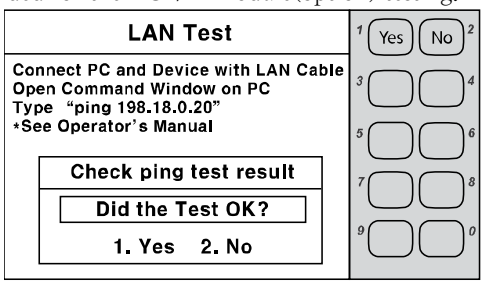


Figure 4-11 LAN Test

1. Enter the LAN Test menu. (Figure 4-11)
2. Connect PC and the device with cross cable directly
3. Please wait until the 'limited connection' icon( ) on the icon tray of windows.
4. Run a command window and type "ping 192.18.0.20".

*Start〉Run〉cmd

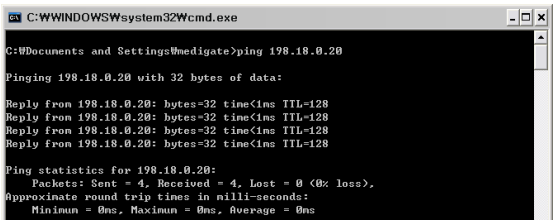

C:₩WINDOWS₩system32₩cmd.exe
C:₩Documents and Settings₩medigate>ping 198.18.0.20
Pinging 198.18.0.20 with 32 bytes of data:
Reply from 198.18.0.20: bytes=32 time<1ms TTL=128
Reply from 198.18.0.20: bytes=32 time<1ms TTL=128
Reply from 198.18.0.20: bytes=32 time<1ms TTL=128
Reply from 198.18.0.20: bytes=32 time<1ms TTL=128
Ping statistics for 198.18.0.20:
Packets: Sent = 4, Received = 4, Lost = 0 (0% loss),
Approximate round trip times in milli-seconds:
Minimum = 0ms, Maximum = 0ms, Average = 0ms

Figure 4-12 LAN Test(ping Test)

5. "Lost = 0 〈0%loss〉" means passed the test

4.5.8 SD Card Test

This test is provided to check the external storage device. (SD card, option)

4.5.9 Voltage Level Test

This menu checks the voltage level of major modules in the device. The test is will be start automatically when entered this menu.

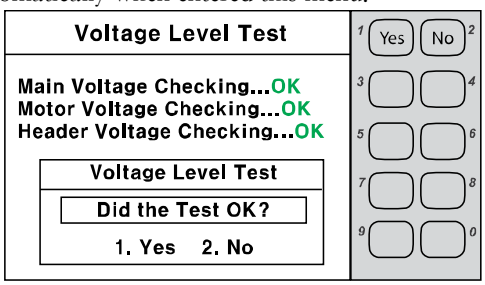


Figure 4-13 Voltage Level Test

4.5.10 Patient Cable Test

This test is provided to check the patient cable. Connect all leads with a ECG simulator or short all leads.

4.5.11 ECG Acquisition Module Test

This test is provided to check the ECG acquisition module. If this test is not passed, please contact to service center.

4.5.12 Print Test Result Summary

This menu is located second page of Maintenance menu. It shows summary of tests result. Figure 4-12 shows test result summary. OK means the test is passed, Fail means the test is not passed, N/A means the test is not performed. This result summary page is printable and useful when you ask some technical support.

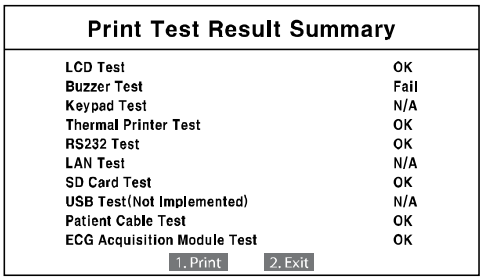


Figure 4-14 Print Test Result Summary

4.6 Battery Maintenance

If the device has not been used 2 or more months, the internal battery will be exhausted. If battery operation is needed at exhausted battery situation, connect AC power line more than 6 hours for charging.

The battery should be removed from the device if placed in storage or will not be used for a long period. Refer to the service manual for battery replacement.

4.7 Firmware Update

The YM303i is designed to updateable its firmware for performance enhancement or firmware recovery. Firmware update is using USB memory device. Depend on memory bender it may be incompatible with the YM303i. If upgrade fails try using different bender's memory. If any problem during firmware update, contact the MEDIANA service center.

Caution: Battery operation hazard
Operate with AC power. Do not off power during firmware update. If lost power during firmware update it may serious error occurred.

Caution: Trained personnel or service engineer only
Firmware update is effect on all the operations, so firmware update is doing by trained personnel or service engineer.

Caution: All setting values will be lost
All setting values of Automatic mode Setup, Manual mode Setup and System Setup will be lost during firmware update.

Caution: Default set after firmware update
After new firmware update completed, the device should set to the default. If not set to default, the device is not normal operation.

1) Connect the YM303i with AC power line.

2) All setting value of Automatic mode setup, Manual mode setup and System setup will be lost during firmware update. Before firmware updating, please print out setting value of the device.
**MENU>System Setup>Print Setup Menu List*

3) Turn the YM303i off.

Press the power button to tune the device off.

4) Preparing a firmware saved USB memory.
Important: firmware file must located in "\update" folder. Make a "\update" folder at root folder and copy the firmware file.
Ex)If USB memory device has E drive: E:\update\YM303i-Vx.xx.bin

5) Connect USB memory and YM303i.

6) Turn the device on

Press the power button to tune the device on.

7) Press the ESC button and the ENTER button, during start-up screen shows to enter the firmware update mode.

Press the ECS button and the ENTER button to firmware update mode. If not recognized the USB memory or not found firmware file then the device will be boot as normal mode.

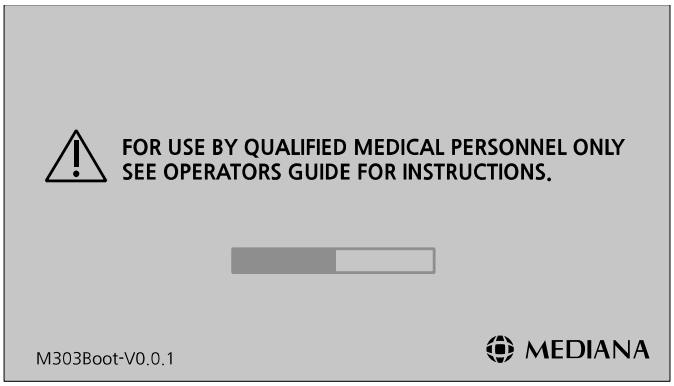


Figure 4-15 Startup Screen

8) When firmware file is recognized the firmware update procedure will be start.

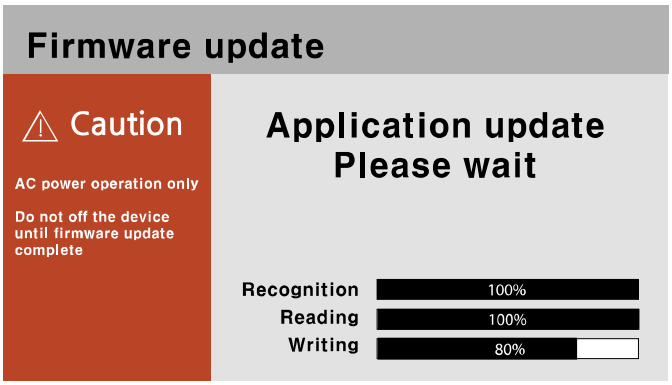


Figure 4-16 Application Update

9) After firmware update complete turn off the device and remove the USB memory device.

10) Turn the device on and set to default setting.

**Default Setting will be found at MENU 〉System Setup*

Chapter5.

Troubleshooting

Chapter5. Troubleshooting

Warning: Due to the risk of electrical shock, do not open the cover of the equipment unless absolutely necessary and disassembly of the machine should be done only by a maintenance worker who has the license from MEDIANA Co., Ltd.

MEDIANA Co., Ltd. Service center
TEL (+82) 70-7092-9967
FAX (+82) 33-742-5483

5.1 Possible problems and solutions

Table 5-1. Possible problems and solutions list

Problem	Check	Possible Solutions
I can't turn on the device.	Check if the AC power line is disconnected. Check if the internal battery needs charge.	The battery needs connect AC power line to charge at least 6 hours.
The battery is not charged or too short operating	Is the battery fully charged?	
	Is the battery used more than 6 month?	The battery is replaced. We recommend replace old battery with new one, supplied by MEDIANA Co., Ltd.
LCD is too dark	Menu〉System Setup〉 LCD light off setting	The power save mode may operate. If any button is pressed LCD back light will be turned on.
	Menu〉System Setup〉 LCD Brightness setting	Adjust LCD Brightness value. Bigger value is brighter.
Abnormal overlapped display shown	Is an error message occurred?	See the 5.2 Error message descriptions and follow it and restart device.
Device dose not respond to any button pressed.	Is an error message occurred?	See the 5.2 Error message descriptions and follow it and restart device.
The height of ECG wave is too big or too small	Check the gain value.	The gain value decides height of ECG signal. Adjust the **Gain** value.(recommend: 10mm/mV)
The length ECG wave is too short or too long.	Check the speed value.	The speed value decides length of ECG signal. Adjust the **Speed** value.(recommend : 20mm/s) If you want 2.5sec, 5sec or 10sec. printing, the report format should be changed. *Menu〉Auto/Manual〉Report Format

Table 5-1. Possible problems and solutions list(continued)

Problem	Check	Possible Solutions
I can't recognize ECG signal. Too much noise added in ECG wave. ECG wave is too small. Unexpected interpretation result shows up.	Check electrodes if it puts wrong place or comes off?	All the electrode needs to acquit ECG signal make sure all electrodes puts right place and contacts well.
	Check if electrodes got any damaged.	The electrodes should be replaced new one, supplied by MEDIANA Co., Ltd.
	Check if patient cable got any damaged or too old.	The patient cable should be replaced new one, supplied by MEDIANA Co., Ltd.
	Check if the place is not clean.	If patient's skin is too dry put some water, and if too much hair at the electrode attaching place then it needs shaving.
	Is the RUN button pressed immediately after electrode attached?	ECG signal needs time to become stable. Check the ECG signal using LCD and press the RUN button to print.
	Check if the patient, patient cable or device did contact during operation.	The patient, patient cable or device dose not contact during operation.
	Are there any heavy energy consume electrical devices operation near the patient bed?	When YM303i is operated with heavy energy consume electrical devices, i.e. electric blanket, electric heater or electric cooker, may cause heavy noise in ECG signal.
	Verify setting of the filters?	Set that the AC filter is compatible with the local supply voltage and frequency. HPF=0.16Hz, LPF=100Hz, AFS=On are recommended.
Printer works but paper does not come. Printer ejects blank paper continuously.	Is the printer cover opened?	Close the printer cover.
	Is the paper loaded on position?	Refer to Chapter4. Device maintenance and verifying the paper direction.
	Is the loaded paper supplied by MEDIANA Co., Ltd.?	Z-fold paper should use MEDIANA Co., Ltd. supplied.
	Check if the loaded paper type and setting value is matched.	Set that the paper type as loaded paper. [Menu>System Setup>Paper Select]
Printer works but some line doesn't print.	Check if the printer of paper got dirty.	Refer to Chapter4. Device maintenance and cleaning the thermal printer.
Printer crumples up paper.	Check the Paper guide.(when roll paper use only) Check the print cover if it is opened. Check the paper loaded at center of the paper container.	Refer to Chapter4. Device maintenance and loading the paper.

5.2 Error message descriptions

The following errors are may occurred at YM303i to notify the user to take the necessary response.

5.2.1 Critical error

This message with warning beep appears when the device occur the critical problem. After that, the device automatically shut down. After a while, turn on. If problem persists, contact qualified service personnel or MEDIANA service center.

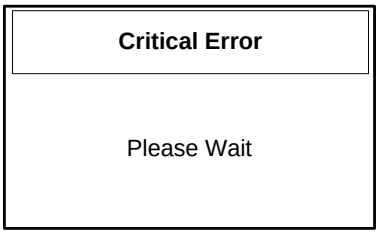


Figure5-1 Critical error

5.2.2 Low Battery I

This message is occurred when not enough battery to any operation. When this message shows up all operations are stopped and turned off. YM303i needs AC power connection immediately and the battery should be charged.

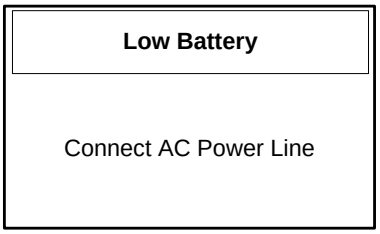


Figure5-2 Low Battery error I

5.2.3 Low Battery II

This message is occurred when not enough battery to print operation. Connect AC power line with YM303i to print operation.

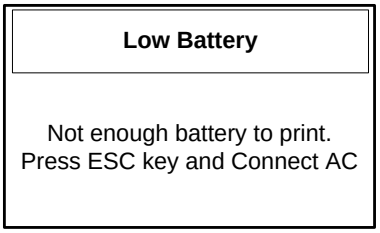


Figure5-3 Low Battery error II

5.2.4 Printer Cover Open or End of Paper

This message is occurred with beep sound when printing start or printing with printer cover is opened or no paper in printer conditions.

At printing start: The message shows up with 4times beep sound.

At printing: Automatic mode–The message shows up with 4times beep sound. Manual mode–The message shows up with beep sound until STOP button is pressed or new paper is reloaded.

.

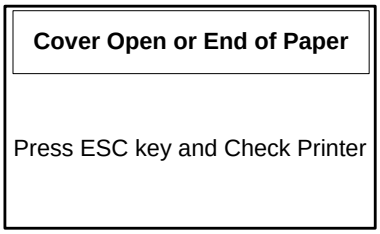


Figure5-4 Printer cover open or No paper detect

5.2.5 Paper Type Error

This message means setting paper type and loaded paper type is not matched. Set the paper type at [MENU > System Setup > Paper Select].

When paper type is set to Roll and Z-fold paper is loaded, it will be not occurred error massage.

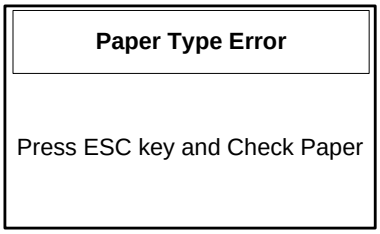


Figure5-5 Printer Type Error

5.2.6 Patient ID Check Error

This message is occurred when **RUN** button is pressed at [MENU > System Setup > Patient Data Entry > Pat. ID Check] set to "Yes" but not entered patient ID. Input the patient ID or [MENU > System Setup > Patient Data Entry > Pat. ID Check] set to "No".

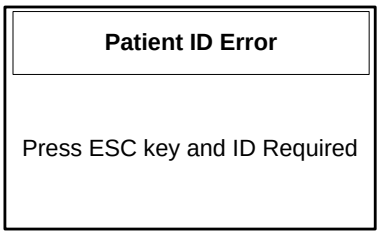


Figure5-6 Patient ID Check error

5.2.7 Save Error I

This message is occurred when **Save** button is pressed at [MENU > System Setup > Patient Data Entry > Pat. ID Check] set to "Yes" but not entered patient ID. Input the patient ID or [MENU > System Setup > Patient Data Entry > Pat. ID Check] set to "No".

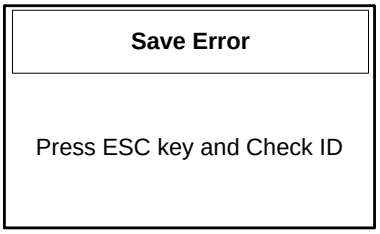


Figure5-7 ID Check error

5.2.8 Save Error II

This message is occurred when **Save** button is pressed at [Manual Mode].
The ECG data save function is valid only [Automatic mode].

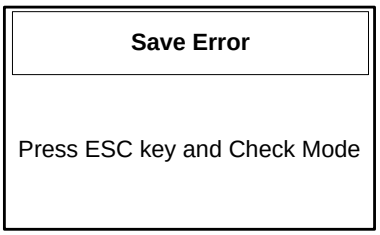


Figure5-8 Mode error

5.2.9 Save Error III

This Message is occurred when Save button is pressed without ECG measurement. Please try again after ECG measurement at [Automatic mode].

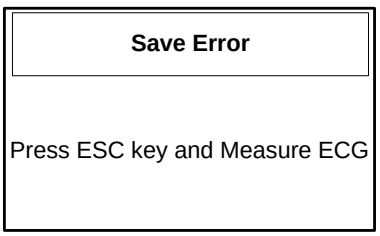


Figure5-9 ID Data empty error

5.2.10 Date Input Error

This message with warning beep appears when the date is not entered or is out of the realistic range (month: 1~12, day: 1~31). Check the date and then, input again.

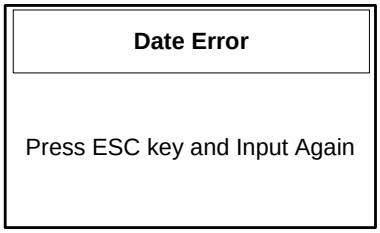


Figure5-10 Date input error

5.2.11 Time Input Error

This message with warning beep appears when the time is not entered or is out of the realistic range (min: 1~59, hour: 1(0)~12(24)). Check the time and then, input again.

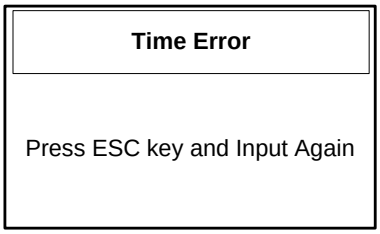


Figure5-11 Time input error

5.2.12 Figure Input Error

This message means not valid number typed. Each IP addresses field can have a value from 0 through 255. Please type valid number.

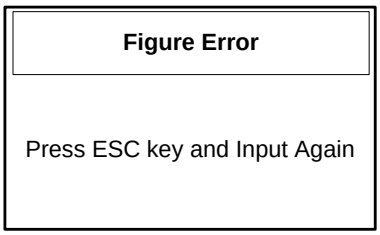


Figure5-12 Figure input error

5.2.13 Password Input Error

This message means entered password is not matched.

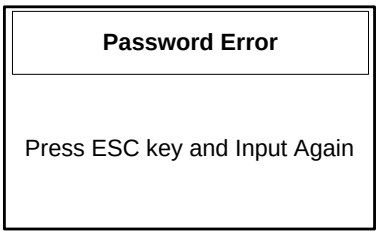


Figure5-13 Wrong Password error

5.2.14 Copy Error I

[Manual Mode] doesn't have Copy operation. This message means the **Copy** button is pressed at [Manual mode]. Change the operation mode to [Automatic mode].

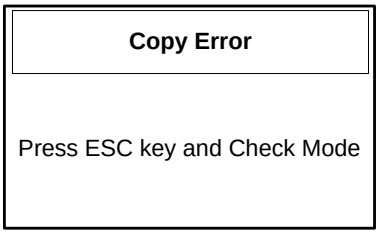


Figure5-14 Copy error I

5.2.15 Copy Error II

The Copy function prints using previous ECG data, which acquitted at [Automatic mode]. This message means there are no available data in buffer.

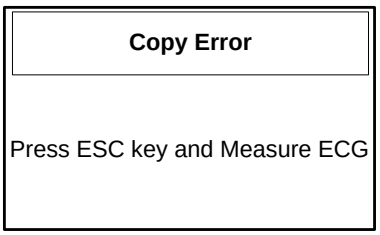


Figure5-15 Copy error II

5.2.16 Delete Error

This message is occurred when you trying delete at [File Management] menu. It means there are no data to delete in selected storage(Internal memory or SD card).

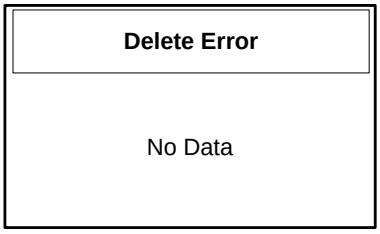


Figure5-16 Delete error

5.2.17 Change Error

This message occurred when you trying **Change** function but there are no ECG data saved to change in Internal Memory or SD Card.

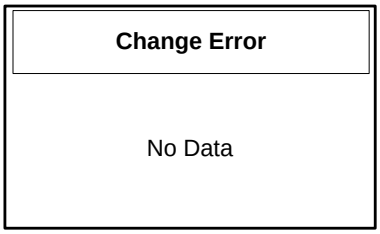


Figure5-17 Change error

5.2.18 Send Error

This message occurred when you trying **Send** function but there are no ECG data saved to change in Internal Memory or SD Card.

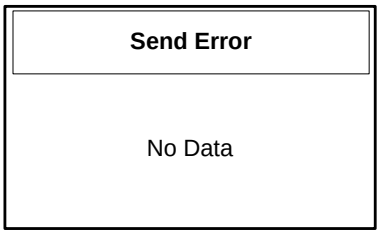


Figure5-18 Send error

5.2.19 Print Error

This message occurred when you trying **Print** function but there are no ECG data saved to change in Internal Memory or SD Card.

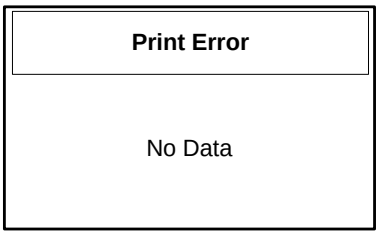


Figure5-19 Print error

5.2.20 Print Directory Error

This message occurred when you trying **Print Directory** function but there are no ECG data saved to change in Internal Memory or SD Card.

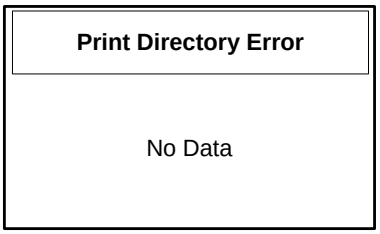


Figure5-20 Print Directory error

5.2.21 Input Saturation Warning Error

OVER This message with warning beep appears when the analog signal saturate. It is displayed on Signal Quality Indication section(see s3.1.3 Home Screen). It will be adjusted automatically, pleas wait until ECG signal is stabled and try again.

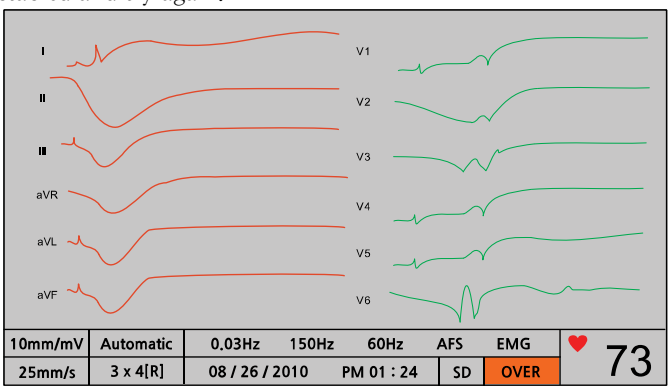


Figure5-21 Saturation warning

5.2.22 Pre-Sample Error

This message means [Menu 〉 System Setup 〉 ECG Sample Acquisition] is set **Pre** but not enough samples in the buffer to analyze. Pleas wait more than 10second after YM303i is turned on or any menu screen is closed.

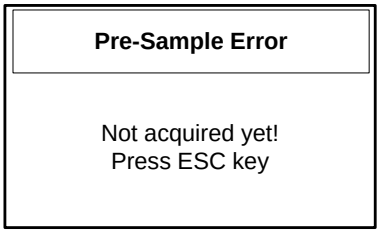


Figure5-22 Print Directory error

5.2.23 Update Error I

This message means device could not recognition a USB memory device. Please check the USB memory device.

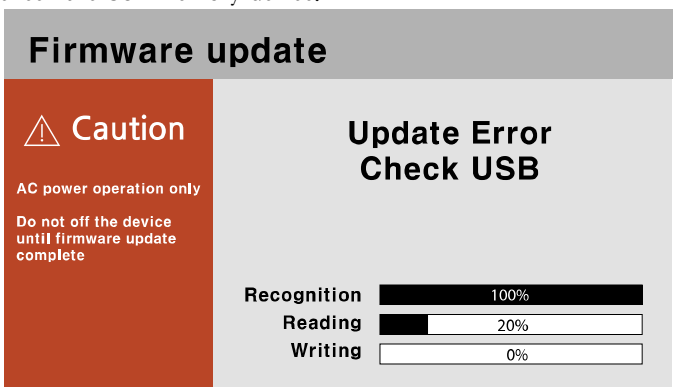


Figure5-23 Update Error I

5.2.24 Update Error II

This message means there are no firmware data file(*.bin) to update. It is occurred when;

1) installed version is newer than the version you trying to update,
2) installed version is same version you trying to update,
3) other model's firmware file.

Check the version and model of the firmware file.

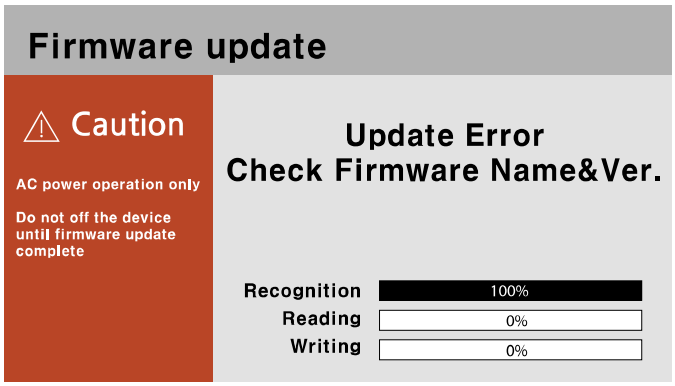


Figure5-24 Update Error II

5.2.24 Update Error III

This message occurred when not enough internal power to firmware update. Please connect AC power line and try again.

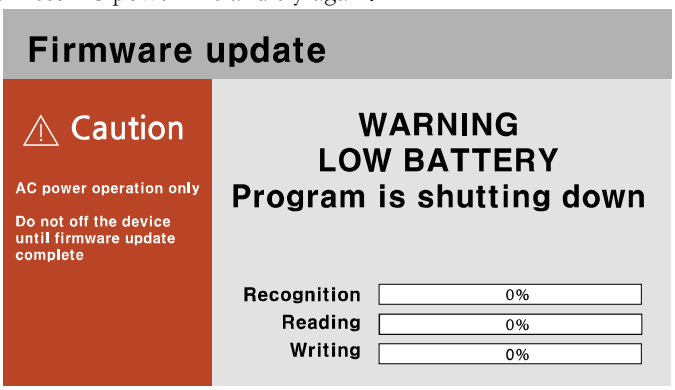


Figure5-25 Update Error III

Chapter6.

Specification

Chapter6. Specification

Display	
Type	4.3 inch color TFT LCD
Resolution	480 X 272 dots

Computerized Electrocardiograph	
Acquisition & Analysis	12Leads simultaneously
ECG Storage	Internal: 100 ECGs External(Option): 5000 ECGs in SD Card
Dynamic Range	AC differential: ±5mV DC offset: ±300mV
Sampling Rate	2000 samples/second/channel
Frequency Response	0.04 to 150Hz
Common Mode Rejection	≥ 100dB
Input Impedance	≥ 10㏁
Communication	PC communication with RS232 interface or LAN(Option)
Firmware Update	Using a USB memory device
Filter	AC Line Filter: 50, 60Hz Low Pass Filter: 40, 100, 150Hz High Pass Filter: 0.04, 0.05, 0.16, 0.1, 0.3Hz Muscle Filter: 25, 35Hz Anti-Floating System(AFS)

Writer	
Type	Thermal dot array (Voltage axis: 8dots/mm, Time axis: 16dots/mm)
Numbers of Traces	3 or 6 user-selectable
Speeds	5, 10, 25, 50mm/sec
Gain	5, 10, 20mm/mV
Speed Accuracy	±5%
Amplitude Accuracy	±5%
Paper Type and Size	Roll: 80mm(W) X 30m(L) Z-fold: 80mm(W) X 80mm(L) X 300(sheets)

Electrical	
Power Supply	AC or Battery operation
AC Input	100-240VAC, 50/60Hz, 70VA
Fuse	Qty2, 250Vac T3.15A in primary circuit Qty1, 250Vac T6.3A in battery protection
Battery Type	Rechargeable Nickel Metal Hydride Cylindrical Cell Standard: 9.6V 2700mAh, Large: 9.6V 3800mAh
Battery Capacity	Standard: 100 basic reports (Automatic Mode) or 3hours continuous operation (without printing) Large: 200 basic reports (Automatic Mode) or 4hours continuous operation (without printing)
Battery Charge Time	Approximately 5hours

Physical	
Dimension	311 X 242 X 85 (W x L x H) mm
Weight(without paper)	Approximately 2.4kg

Environmental	
Operating Conditions	Temperature range 10-45℃ Humidity range 20%~95%(non-condensing) Atmosphere Pressure: 700 to 1060 hPa
Storage/Transportation Condition	Temperature range -15~50℃ Humidity range 20%~95%(non-condensing) Atmosphere Pressure: 500 to 1060 hPa

Compliance	
Classification	Class I, Internally powered
Type of protection	Type CF with defibrillation protection
Patient Leakage Current	< 10㎂
Mode of operation	Continuous
Degree of protection	IPX 0
General	EU Directives for medical devices (93/42/EEC as amended by 2007/47/EC)
	ISO13485:2003 Medical devices - Quality management systems - Requirements regulatory purposes
	ISO14971:2007 Medical devices - Application of risk management to medical devices
	IEC60601-1: 1988+A1:1991+A2:1995 General requirements for Safety
	IEC60601-1-4: 2000 General Requirements for safety - Collateral standard: Programmable electrical medical systems
	ISO10993-1: 2003 Biological evaluation of medical devices - Part 1: Evaluation and testing

Compliance (continued)	
Electrocardiograph	IEC60601-2-25:1993+A1:1999 Particular requirements for the safety of electrocardiographs
Electromagnetic Compatibility	IEC60601, sub clause 36
	IEC60601-1-2: 2007 Electromagnetic compatibility - Requirements and tests
	IEC61000-3-2:2000 Harmonic current emissions
	IEC61000-3-3:1995+A2:2005 Voltage fluctuations/Flicker Emissions
	IEC61000-4-2:1995+A1:1998+A2:2001 Electrostatic Discharge(ESD)
	IEC61000-4-3:2006 Radiated RF electromagnetic field
	IEC61000-4-4:2004 Electrical fast transient/burst
	IEC61000-4-5:2006 Surge current
	IEC61000-4-6:2007 Conducted disturbances, induced by RF field
	IEC61000-4-8:1993+A1:2001 Power frequency(50/60Hz) magnetic field
	IEC61000-4-11:2004 Voltage dips, short interruption and voltage variation on power supply input lines
	CISPR11(EN55011) RF Emissions Group 1, Class B
Labeling	EN1041:1998 Information supplied by the manufacturer with medical devices
Marking	EN980:2003 Graphical symbols for use in the labeling of medical devices

Manufacturer's Declaration

Warning: For best product performance and measurement accuracy, use only accessories supplied or recommended by manufacturer. Use accessories according to the manufacturer's directions for use and your facility's standards. The use of accessories and cables other than those specified may result in increased emission and/or decreased immunity of the YM303i electrocardiograph.

The YM303i Electrocardiograph is suitable for use in the specified electromagnetic environment. The customer and/or user of the YM303i electrocardiograph should assure that it is used in an electromagnetic environment as described below.

Table 6-1. Electromagnetic Emissions (IEC60601-1-2)

Emission Test	Compliance	Electromagnetic Environment - guidance
RF emission CISPR 11	Group 1	The YM303i electrocardiograph uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Complies	

Table 6-2. Electromagnetic Immunity (IEC60601-1-2)

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic Environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *UT* (>95 % dip in *UT*) for 0,5 cycle 40 % *UT* (60 % dip in *UT*) for 5 cycles 70 % *UT* (30 % dip in *UT*) for 25 cycles <5 % *UT* (>95 % dip in *UT*) for 5 sec	<5 % *UT* (>95 % dip in *UT*) for 0,5 cycle 40 % *UT* (60 % dip in *UT*) for 5 cycles 70 % *UT* (30 % dip in *UT*) for 25 cycles <5 % *UT* (>95 % dip in *UT*) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the YM303i electrocardiograph requires continued operation during power mains interruptions, it is recommended that the YM303i electrocardiograph be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *UT* is the a.c. mains voltage prior to application of the test level.			

Table 6-3. Electromagnetic Immunity (IEC60601-1-2)

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic Environment - guidance
The YM303i electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the YM303i electrocardiograph should assure that it is used in such an environment.			
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80MHz to 800MHz 3 V/m 800MHz to 2.5GHz	3Vrms 3 V/m 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the YM303i electrocardiograph, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommend separation distance** $d = 1.2\sqrt{p}$ $d = 1.2\sqrt{p}$ 80MHz to 800MHz $d = 2.3\sqrt{p}$ 800MHz to 2.5GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the YM303i electrocardiograph is used exceeds the applicable RF compliance level above, the YM303i electrocardiograph should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the YM303i electrocardiograph.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 6-4. Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the YM303i electrocardiograph			
The YM303i electrocardiograph is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the YM303i electrocardiograph can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the YM303i electrocardiograph as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output power of Transmitter in watt	**Separation distance according to frequency of transmitter in meter**		
	150 kHz to 80 MHz $d = 1.2\sqrt{p}$	**80MHz to 800MHz** $d = 1.2\sqrt{p}$	**800MHz to 2.5GHz** $d = 2.3\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres(m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Table 6-5. Cables (IEC60601-1-2)

Cables	**Length(m)**	**Complies with**
Power cable, Unshielded	1.8	- RF emissions, CISPR 11, ClassB/Group1 - Harmonic emissions, IEC61000-3-2 - Voltage fluctuations/flicker emission, IEC61000-3-3 - Electrostatic discharge(ESD), IEC61000-4-2 - Electric fast transient/burst, IEC61000-4-4 - Surge, IEC61000-4-5 - Conducted RF IEC61000-4-6 - Radiated RF, IEC61000-4-3
RS232C cable, Shielded	1.8	
LAN cable, Shielded	20.0	
ECG Lead cable, Shielded	3.7	